

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 19-97 (CFC)(CJB)

REDACTED - PUBLIC VERSION

Original filing date: June 9, 2022

Redacted filing date: June 16, 2022

JOINT [PROPOSED] PRETRIAL ORDER
(Volume 2 of 2)

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Rodger D. Smith II (#3778)
Anthony D. Raucci (#5948)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
rsmith@morrisnichols.com
araucci@morrisnichols.com

OF COUNSEL:

Ashok Ramani
David J. Lisson
Micah G. Block
Philip T. Sheng
Ian Hogg
DAVIS POLK & WARDWELL LLP
1600 El Camino Real
Menlo Park, CA 94025
(650) 752-2000

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Nicole K. Pedi (#6236)
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
pedi@rlf.com

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000

Kathryn B. Bi
Alena Farber
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, NY 10017
(212) 450-4000

Attorneys for Defendant

Attorneys for Plaintiff

June 9, 2022

EXHIBIT 15

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 15

**MAGNOLIA’S MOTION *IN LIMINE* NO. 2:
TO EXCLUDE EVIDENCE OR ARGUMENT THAT MAGNOLIA
DRAFTED THE ASSERTED CLAIMS TO COVER THE KURIN LOCK
AND ANY REFERENCE TO THE TIMING OF THE ASSERTED
PATENTS RELATIVE TO THE RELEASE OF THE KURIN LOCK**

Magnolia moves to exclude any evidence or argument that Magnolia drafted the asserted claims to cover the Kurin Lock as well as any reference to the timing of the patents-in-suit relative to the release of the Kurin Lock.

The patents-in-suit claim priority to provisional patent applications filed in 2006 and 2011, long before Kurin launched the accused Kurin Lock in May 2017. U.S. Pat. No. 9,855,001 (the “’001 Patent”); U.S. Pat. No. 10,039,483 (the “’483 Patent”). However, the patents did not issue until after the launch. Magnolia filed its application for the ’001 Patent in March 2017, and the patent issued in January 2018. Magnolia filed its application for the ’483 Patent in December 2017, and the patent issued in August 2018. In light of these dates, Kurin has alleged that Magnolia wrote the ’001 and ’483 Patent claims to cover the Kurin Lock and that Magnolia’s filing of continuation applications was somehow improper. Ex. 15.1 (Claim Construction Hr’g Tr.) at 43:14–44:4, Apr. 5, 2020 (complaining about Magnolia’s continuations and that Magnolia wrote claims “in the context of having seen the Kurin device on the market”). The Court should preclude Kurin from making such assertions in front of the jury.

Whether Magnolia drafted claims to cover the Kurin Lock is irrelevant. “There is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market; nor is it in any manner improper to amend or insert claims intended to

cover a competitor’s product the applicant’s attorney has learned about during the prosecution of a patent application. . . . [A claim’s] genesis in the marketplace is simply irrelevant[.]” *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988); *see also Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir. 1998); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 (Fed. Cir. 2004). Moreover, suggesting that Magnolia wrote claims to cover Kurin’s product would confuse and mislead the jury to believe that Magnolia “took improper advantage of the patent system” or otherwise behaved in an “unprincipled” way. *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, C.A. No. 2:15-1202-WCB, 2017 WL 959592, *1–*3 (E.D. Tex. Mar. 13, 2017) (Bryson, J., sitting by designation). In order to prevent such prejudice, the Court should preclude Kurin from doing so. *Id.*

The Court should also exclude any comparison of the filing and issue dates of the patents-in-suit relative to the release of the Kurin Lock for similar reasons. Certainly, reference to the patents’ issue dates in isolation is not improper. However, connecting or comparing the filing and issue dates to the release of the Kurin Lock is not relevant. Infringement began when patents issued and the infringement, invalidity, and damages analyses are the same regardless of how much earlier Kurin released the accused product. Kurin’s written-description defense, for example, simply requires a comparison of the claims to the

specification. And Magnolia's willfulness claim is based on years of Kurin misconduct both before and after the patents issued, including [REDACTED]

[REDACTED]

[REDACTED] *See*

D.I. 344 at 1–7, 10–14. [REDACTED]

[REDACTED]

[REDACTED] D.I. 346, Ex. 1 at 521:6–20.

Kurin's knowledge and behavior is what is relevant, not the fact that Magnolia asserts continuation patents that issued after Kurin's product launched.

There is nothing improper about Magnolia's filing of continuation applications, but jurors unfamiliar with patent law and prosecution might mistakenly believe otherwise when faced with a comparison of the timing of the patents-in-suit and launch of the accused product. Magnolia and the Court would thus be required to spend time explaining the continuation application process and the fact that it is both common and proper. Even then, jurors are likely to be confused as to how a product can infringe a patent filed or issued after its launch. The Court should thus exclude such confusing and prejudicial comparisons.

EXHIBIT 15.1

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

MAGNOLIA MEDICAL : CIVIL ACTION
TECHNOLOGIES, INC., :
 :
Plaintiff, :
 :
 :
vs. :
 :
 :
KURIN, INC., :
 :
 :
Defendant. : NO. 19-00097-CFC

- - -

Wilmington, Delaware
Wednesday, April 15, 2020
9:15 o'clock, a.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

FISH & RICHARDSON P.C.
BY: DOUGLAS E. McCANN, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

1 operable to transition to the second state without manual
2 intervention as a direct result of filling the contaminant
3 reservoir, that to me falls within the functionality that is
4 addressed in MTD, and it would it seems to me then leave it
5 to the defendant to show whether there is a failure of the
6 claim to recite sufficient structure, and if it does, then
7 it seems to me means-plus-function applies, speaking solely
8 with respect to claim 17.

9 So can I hear from the defendant?

10 MR. HANGARTNER: Yes, Your Honor. So this is
11 the same problem we had before. There is again insufficient
12 structure to perform this function of directing the flow
13 path.

14 So I think first I just want to take one second
15 to talk a little bit about how we got here with these
16 claims. This '689 patent is the tenth continuation in this
17 family, so there are ten tries trying to come up with the
18 claim and really configure what they are trying to claim
19 from this very simple patent that discloses two structures
20 for diverting flow down one of two paths.

21 And they are writing these claims in the context
22 of having seen the Kurin device on the market for a couple
23 of years, and they are trying desperately to write a claim
24 that they can massage into a form that they think they can
25 file the case that we're dealing with right now.

1 So this is all premeditated. This is all
2 carefully crafted. They've tried dozens of different claim
3 formulations to come up with something they can read in
4 context. So within that context we now look at this claim
5 and what we see is the same problem that we saw with
6 diverter. There is not sufficient structure here to perform
7 the claimed function.

8 A junction, we don't disagree with what a
9 junction is in the normal world. A junction is a place and
10 it's an intersection and using the patent, and as used in
11 this patent, there's one reference to the word junction in
12 the specification.

13 THE COURT: So --

14 MR. HANGARTNER: And --

15 THE COURT: Sorry to interrupt, but I did say
16 60 minutes and we're already past that. So can you just cut
17 right to the chase? What's the structure that's lacking in
18 claim 17 that makes it means-plus-function?

19 MR. HANGARTNER: There's no structure to perform
20 the transition.

21 THE COURT: Okay. What does the structure
22 accomplish via the functionality, the transition? So, you
23 know, you did this earlier on in a pretty succinct way. Do
24 you want to just do that?

25 MR. HANGARTNER: Yes. So the junction, the

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**KURIN’S OPPOSITION TO MOTION *IN LIMINE* NO. 2: TO EXCLUDE
EVIDENCE OR ARGUMENT THAT MAGNOLIA DRAFTED THE
ASSERTED CLAIMS TO COVER THE KURIN LOCK AND ANY
REFERENCE TO THE TIMING OF THE ASSERTED PATENTS
RELATIVE TO THE RELEASE OF THE KURIN LOCK**

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP

1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000

RICHARDS, LAYTON & FINGER, P.A.

Kelly E. Farnan (#4395)

Richards, Layton & Finger, P.A.

920 N. King Street

One Rodney Square

Wilmington, DE 19801

(302) 651-7700

Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

May 27, 2022

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Bioverativ Inc. v. Behring LLC</i> , 2020 WL 1332921 (D. Del. Mar. 23, 2020)	3
<i>Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.</i> , 2017 WL 959592 (E.D. Tex. Mar. 13, 2017)	1, 2, 3
<i>Gentry Gallery, Inc. v. Berkline Corp.</i> , 134 F.3d 1473 (Fed. Cir. 1998)	2
<i>Sri Int’l, Inc. v. Cisco Sys., Inc.</i> , 930 F.3d 1295 (Fed. Cir. 2019)	3
<i>State Indus., Inc. v. A.O. Smith Corp.</i> , 751 F.2d 1226 (Fed. Cir. 1985)	3

Statutes

35 U.S.C. § 112	2
-----------------------	---

Evidence of the timing of the patents-in-suit relative to the release of the Kurin Lock is highly relevant to Kurin's defenses in both phases of this case. Explaining that Magnolia had the opportunity during claim drafting to crib contested claim terms from publicly available Kurin Lock documents is key to rebutting Magnolia's attempt to depict Kurin's legacy use of such terms as admissions of infringement and evidence of willfulness. Magnolia's own caselaw shows such relevant evidence should be admitted. *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 2017 WL 959592, at *1, (E.D. Tex. Mar. 13, 2017) (allowing evidence "for any purpose relevant to a claim or defense in this case").

Magnolia prosecuted an extensive patent portfolio before the release of the Kurin Lock, but none of these patents, unasserted here, actually covered it. After Kurin Lock and descriptions thereof became publicly available, Magnolia changed course and drafted the Asserted Claims using terms such as "divert" and "sequester" that Kurin had publicly used in describing the Kurin Lock. *See* Ex. 1, PTX-0019 (12/2016 Kurin Lock FDA clearance with Device Description). Magnolia has made clear that in seeking to prove direct infringement in Phase 1, it will overwhelmingly focus on such legacy Kurin descriptions, rather than on the direct evidence available regarding the actual design and function of the Kurin Lock.¹ *See* Kurin's MIL No. 3; Ex. 1 (listing 23 Kurin FDA documents before any

¹ Kurin's motion *in limine* No. 3 addresses such improper infringement arguments.

drawings or videos of the device). If Magnolia is thus permitted to paint Kurin's descriptions as admissions of infringement, Kurin must be allowed to explain that Magnolia drafted the claims after Kurin's device, and the descriptions thereof, were made public. Otherwise, Magnolia will be able to convey an incomplete and prejudicially misleading impression to the jury about why Kurin's documents use the same words used in the Asserted Claims. Notably, the jury will already have the facts underlying this chronology—the dates of filing and issuance (which are reflected on the face of the patents-in-suit) and Kurin Lock's launch.

In Phase 2 these facts are relevant to Kurin's § 112 defenses and to rebutting Magnolia's willfulness claim. First, Magnolia's own caselaw recognizes this evidence is relevant to Kurin's written description defenses based on Magnolia's overreach in drafting claims to cover the Kurin Lock. *Erfindergemeinschaft*, 2017 WL 959592, at *3; *see also Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998) (drafting claims broadly after becoming aware of competitive products is relevant to, and supported a finding of, invalidity under § 112). Second, courts have consistently relied on such evidence as refuting willfulness based on the type of pre-patent issuance evidence on which Magnolia relies.² On exactly these facts, the Federal Circuit found no willfulness, pointing to a chronology in which patentee's original unasserted patents did not cover the

² Kurin's motion *in limine* No. 2 addresses such improper willfulness evidence.

accused product, but then after examining the accused product the patentee “commenced its efforts in the PTO to obtain claims” to cover the accused product, which “had been designed and built before the progenitors of claims 7 and 8 in suit were submitted to the PTO.” *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235 (Fed. Cir. 1985). This “familiar picture”, where a patentee thus “manipulat[es] its secret pending patent application to cover the functionally competitive structure it did *not* think of but deems to embody its proprietary ‘inventive concept’” is “classic commercial gamesmanship under the patent system” that does not support willful infringement. *Id.* Other recent cases also rely on the chronology of events relative to the filing date as negating the requisite intent for willfulness. *Sri Int’l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019) (“[T]he parent ’203 patent was not even filed until several months after the parties met.”); *Bioverativ Inc. v. Behring LLC*, 2020 WL 1332921, *3 (D. Del. Mar. 23, 2020) (“The complained-of development activities all appear to have taken place before the asserted patents’ priority date.”). In stark contrast, the defendant in Magnolia’s lone, inapposite district court case failed to articulate a willfulness defense to which the filing date (rather than just the issuance date) was relevant. *Erfindergemeinschaft*, 2017 WL 959592, at *2–3.

For the foregoing reasons, the Court should deny Magnolia’s motion *in limine*.

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
kraman@paulweiss.com
jreich@paulweiss.com
abarel@paulweiss.com

RICHARDS, LAYTON & FINGER,
P.A.

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

May 27, 2022

I declare under penalty of perjury that the foregoing is true and correct. Executed on May 27, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 1

TRIAL EX.	PHASE 1*	DESCRIPTION	BEG BATES	END BATES	DEPO EXS	KURIN'S OBJECTIONS
PTX-0001	Yes	Official ribbon copy of U.S. Patent No. 10,039,483 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," to Bullington	MAG-DEL0000533	MAG-DEL0000564	Gaw 26 Rogers 18 Miazga 01	
PTX-0002	Yes	Official ribbon copy of U.S. Patent No. 9,855,001 entitled, "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples with Reduced Contamination," to Patton	MAG-DEL0000618	MAG-DEL0000636	Miazga 19 Rogers 17	
PTX-0003	Yes	Prosecution history of U.S. Patent No. 9,855,001 entitled, "Systems and Methods for Complete K162233 510(k) submission	MAG-DEL0001488	MAG-DEL0001747		
PTX-0004	Yes	Kurin document titled as, "Manufacturing Procedure, BCS w/BD Vacutainer, BioMerieux	KUR-MAG-DE488364	KUR-MAG-DE488754		402, 403, 602, MIL
PTX-0005	Yes	Kurin document titled as, "Manufacturing Procedure, Assembly, Kurin Lock, Automation,"	KUR-MAG-DE000075	KUR-MAG-DE000096		402, 403, 602
PTX-0006	Yes	Kurin document titled as, "Attachment 6: Device Description."	KUR-MAG-DE000104	KUR-MAG-DE000124		
PTX-0008	Yes	Document titled, "Substantial Equivalence Discussion."	KUR-MAG-DE000147	KUR-MAG-DE000155	Nason 06	402, 403, 602, MIL
PTX-0009	Yes	Report entitled, "Biocompatibility Review of the Calliope Solutions, Inc. Kurin Blood Culture K162233 Cover Letter	KUR-MAG-DE000156	KUR-MAG-DE000162		402, 403, 602, MIL
PTX-0010	Yes	K162233 Proposed Indications for Use	KUR-MAG-DE000274	KUR-MAG-DE000304	Rogers 35	402, 403, 602, MIL
PTX-0011	Yes	K162233 Truthful and Accuracy Statement per 21 CFR 807.87(k)"	KUR-MAG-DE000605	KUR-MAG-DE000606		402, 403, 602, 802, MIL
PTX-0012	Yes	K162233 Executive Summary	KUR-MAG-DE000608	KUR-MAG-DE000608		402, 403, 602, MIL
PTX-0013	Yes	Correspondence from M. Job to the USFDA, re: Additional Information (K162233)	KUR-MAG-DE000614	KUR-MAG-DE000614		402, 403, 602, MIL
PTX-0014	Yes	Letter from Emily Davis to Regulatory Technology Services LLC re: "Response to email	KUR-MAG-DE000649	KUR-MAG-DE000650		402, 403, 602, MIL
PTX-0015	Yes	Deficiency List from Department of Health & Human Services for K162233, Kurin Blood	KUR-MAG-DE000657	KUR-MAG-DE000657	Rogers 37	402, 403, 602, 802, MIL
PTX-0017	Yes	K162233 Clearance Letter	KUR-MAG-DE000663	KUR-MAG-DE000663		402, 403, 602, 802, MIL
PTX-0018	Yes	DHHS Letter from Tejasri Purohit-Sheth to Mark Job re: "K162233"	MAG-DEL0000663	MAG-DEL0000670		
PTX-0019	Yes	K162233 Clearance Letter, Indications for Use, and 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181895.pdf	KUR-MAG-DE000735	KUR-MAG-DE000743		402, 403, 602, 802, MIL
PTX-0021	Yes	Document titled as, "Kurin PIV Blood Collection Set with Pressure-Rated Extension Set,	MAG-DEL0826409	MAG-DEL0826416		402, 403, 602, 802, MIL
PTX-0023	Yes	Kurin document titled as, "Response to Acceptance Review Notification, Refuse to Accept	KUR-MAG-DE000745	KUR-MAG-DE001048		402, 403, 602, MIL
PTX-0024	Yes	Kurin document titled, "Response to Request for Additional Information for K181895	KUR-MAG-DE001300	KUR-MAG-DE001380		402, 403, 602, 802, MIL
PTX-0026	Yes	Kurin PIV Blood Collection Set with Pressure-Rated Extension Set Deficiency Letter"	KUR-MAG-DE001416	KUR-MAG-DE001618	Nason 04 Rogers 36	402, 403, 602, MIL
PTX-0028	Yes	K181895 Clearance Letter, Indications for Use, and 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181895.pdf	KUR-MAG-DE156631	KUR-MAG-DE156638		402, 403, 602, 802, MIL
PTX-0029	Yes	FDA Premarket Notification Database Entry for K181895, available at: Complete K181832 510(k) submission	MAG-DEL0826426	MAG-DEL0826428		402, 403, 602
PTX-0030	Yes	K191832 Response to Deficiency Letter, dated 1/3/2020	KUR-MAG-DE495421	KUR-MAG-DE496309		402, 403, 602, MIL
PTX-0033	Yes	Email from N. Hartman to B. Rogers et al., re: K181895/S001 was Accepted	KUR-MAG-DE500175	KUR-MAG-DE500687		402, 403, 602, 802, MIL
PTX-0035	Yes	Kurin Drawing Number KUR-2007 (Cap)	KUR-MAG-DE001627	KUR-MAG-DE001627		
PTX-0064	Yes	Kurin Drawing Number KUR-2005 (Top Housing)	KUR-MAG-DE001623	KUR-MAG-DE001624		
PTX-0065	Yes	Kurin Drawing Number KUR-2006 (Bottom Housing)	KUR-MAG-DE001625	KUR-MAG-DE001626		
PTX-0066	Yes	Kurin Drawing Number KUR-8036 (Assembly, Kurin Lock)	KUR-MAG-DE001659	KUR-MAG-DE001659		
PTX-0067	Yes	Kurin Drawing Number KUR-6010 (Hydrophobic Self-Sealing Plug)	KUR-MAG-DE001655	KUR-MAG-DE001655		
PTX-0068	Yes	Kurin Drawing Number KUR-6011 (Umbrella Valve)	KUR-MAG-DE001656	KUR-MAG-DE001656		
PTX-0069	Yes	Kurin Drawing Number KUR-8022 (Set, Kurin 21GA BCS w/ Standard Needle, BD	KUR-MAG-DE001657	KUR-MAG-DE001658		
PTX-0070	Yes	Kurin Lock device schematics	KUR-MAG-DE001621	KUR-MAG-DE001621		
PTX-0071	Yes	Label, Kurin PIV18 Blood Culture Collection Set with Kurin Lock® Technology, collection	KUR-MAG-DE001813	KUR-MAG-DE001813		
PTX-0072	Yes	Label, Kurin 21G Blood Culture Collection Set with Kurin Lock® Technology, collection	KUR-MAG-DE001853	KUR-MAG-DE001853		
PTX-0073	Yes	M-11223 Unit Label	KUR-MAG-DE001885	KUR-MAG-DE001885		
PTX-0074	Yes	M-21221 Unit Label	KUR-MAG-DE001917	KUR-MAG-DE001917		
PTX-0075	Yes	M-21223 Unit Label	KUR-MAG-DE001949	KUR-MAG-DE001949		
PTX-0076	Yes	M-PIV12 Unit Label	KUR-MAG-DE001980	KUR-MAG-DE001980		
PTX-0077	Yes	M-PIV18 Unit Label	KUR-MAG-DE002024	KUR-MAG-DE002024		
PTX-0078	Yes	T-11221 Unit Label	KUR-MAG-DE002156	KUR-MAG-DE002156		
PTX-0079	Yes	T-11223 Unit Label	KUR-MAG-DE002188	KUR-MAG-DE002188		
PTX-0080	Yes	T-21221 Unit Label	KUR-MAG-DE002220	KUR-MAG-DE002220		
PTX-0081	Yes	T-21223 Unit Label	KUR-MAG-DE002252	KUR-MAG-DE002252		
PTX-0082	Yes	Kurin document titled as, "Kurin PIV12 Blood Culture Collection Set with Kurin Lock®	KUR-MAG-DE002283	KUR-MAG-DE002283		402, 403, 602, 802, MIL
PTX-0083	Yes	T-PIV12 Unit Label	KUR-MAG-DE002284	KUR-MAG-DE002284		
PTX-0084	Yes	T-PIV18 Unit Label	KUR-MAG-DE002334	KUR-MAG-DE002334		
PTX-0085	Yes					

* Magnolia provides the marking of evidence by phase herein in reliance on Kurin's May 10, 2022 email confirming that "Kurin will not argue that Magnolia's good-faith disclosures of evidence by phase are binding or preclusive."

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 15

**MAGNOLIA’S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 2:
TO EXCLUDE EVIDENCE OR ARGUMENT THAT MAGNOLIA
DRAFTED THE ASSERTED CLAIMS TO COVER THE KURIN LOCK
AND ANY REFERENCE TO THE TIMING OF THE ASSERTED
PATENTS RELATIVE TO THE RELEASE OF THE KURIN LOCK**

Kurin cites no authority to support the introduction of evidence of Magnolia's purported claim-drafting strategy in Phase One. Opp'n at 1–2. Nor can it. Magnolia's purported conduct is proper, and allegations that Magnolia used Kurin's admissions about its product to draft claims do not make those admissions any less competent evidence of how the product works. Mot. at 1–2. Kurin must not be allowed to imply impropriety where there is none or beguile the jury's sympathy by suggesting Magnolia unfairly entrapped it into infringement.

The Court should also exclude such evidence from Phase Two. Whether an inventor drafted claims on an accused product is not, in itself, relevant to written description. Instead, it *may be* admissible when it is necessary to provide context for other relevant evidence. *See, e.g., Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998) (inventor admitted to having first learned of claim features *from the accused product*). Neither Kurin nor its experts identify any aspect of Kurin's written-description defense that requires such context. As to willfulness, none of the cases Kurin cites found that drafting claims on an accused product refuted willfulness. Instead, each found no willfulness because the infringer *did not know about the patent during an alleged period of willful infringement*. In contrast, [REDACTED]

[REDACTED] Evidence of the origin of Magnolia's claims should therefore be excluded from Phase Two.

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL)	
TECHNOLOGIES, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-97-CFC (CJB)
)	
KURIN, INC.,)	
)	
Defendant.)	
_____)	

EXHIBIT 16

MAGNOLIA’S MOTION *IN LIMINE* NO. 3:
TO EXCLUDE EVIDENCE OR ARGUMENT
DEVIATING FROM CLAIM-TO-PRODUCT COMPARISON

Magnolia moves to preclude Kurin from offering argument or evidence that deviates from a proper claim-to-product infringement analysis through improper embodiment-to-product or product-to-product comparisons.

The “cardinal principle” in any infringement analysis is that “the accused device must be compared to the claims rather than to a preferred or commercial embodiment.” *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1347 (Fed. Cir. 2003); *see also, e.g., Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1286 (Fed. Cir. 2002) (“[I]nfringement is to be determined by comparing the asserted claim to the accused device, not by comparing the accused device to the figures of the asserted patent.”); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1481–82 (Fed. Cir. 1984). This holds true in all patent cases, regardless of whether the plaintiff is asserting infringement literally or under the doctrine of equivalents. *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (“Infringement, literal or by equivalence, is determined by comparing an accused product not with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed claims in suit.”).

The Court should hold Kurin to this principle and exclude any opinion or argument that compares Kurin’s device to Magnolia’s commercial devices or embodiments in its patent specifications. For example, Kurin’s expert opines that

the Kurin Lock does not practice claim 1 of the '001 and '483 patents because (according to Kurin) it does not “sequester” in the same manner as “disclosed embodiments in the specification of the '483 patent and the Magnolia products . . .” Ex. 16.1 (Antonsson Rpt.) ¶¶ 281–87, 372–81. These comparisons to disclosed and commercial embodiments are irrelevant and unfairly prejudicial, particularly given that the Court construed “sequester” as having its plain and ordinary meaning, and *not* any special meaning particular to the patents. D.I. 75 at 2. Similarly, Kurin’s expert improperly compares Kurin’s device to disclosed embodiments when he opines that the Kurin Lock does not have a “vent” because the “hole in the cap of the Kurin device filled by the porous plug does not provide the same function as the vent disclosed in the first embodiment of the '483 Patent.” Ex. 16.1 ¶¶ 400–07; *see, e.g., id.* ¶¶ 387–96 (opining that the Kurin Lock’s porous plug cannot be a “seal member” because “[t]here is no plug that performs a sealing function in the embodiments disclosed in the '483 Patent”); *see also id.* ¶¶ 140–47, 155, 177, 252–53, 264–67, 322–23, 355–57, 372–81, 442–43, 448–49, 486–89.

Courts regularly exclude comparisons like these because they are irrelevant to the infringement analysis and the “risks of jury confusion and prejudice far outweigh the probative value of such evidence.” *Praxair, Inc. v. ATMI, Inc.*, C.A. No. 03-1158-SLR, 2005 WL 3159054, at *2 (D. Del. Nov. 28, 2005). For example, in *Praxair*, the defendant sought to introduce an additional requirement

into the asserted claims based on the operation of the plaintiff's commercial embodiment. *Id.* The Court disagreed, noting that the jury's infringement determination "does not require analysis of the [plaintiff's] product," and that allowing such a comparison would violate clear Federal Circuit precedent. *Id.* Similarly, in *ICU Medical, Inc. v. RyMed Technologies, Inc.*, the Court excluded argument or evidence comparing the accused product to the plaintiff's commercial embodiment. 752 F. Supp. 2d 486, 491 (D. Del. 2010); *see also Intellectual Ventures II LLC v. FedEx Corp.*, No. 2:16-cv-0980, 2018 WL 10638138, at *3 (E.D. Tex. Apr. 26, 2018) (holding that "the only proper comparison is between the accused products and the elements of the Asserted Claims" and precluding comparisons of the "accused systems and methods to any commercial embodiments or prototypes of the asserted patents"); *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, 2016 WL 775742, at *4 (D. Del. Feb. 25, 2016) (precluding testimony that disclosed or commercial embodiments support expert's view of a term's plain and ordinary meaning, because "[s]uggesting, incorrectly, that literal infringement can be established by comparing accused products with specification or commercial embodiments would risk unfair prejudice").

The Court should thus preclude Kurin from offering any evidence or argument that compares the accused products to disclosed or commercialized embodiments.

EXHIBIT 16.1

FILED UNDER SEAL

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Apple, Inc. v. Samsung Elecs. Co.</i> , 2014 WL 660857 (N.D. Cal. Feb. 20, 2014)	3
<i>ECB USA, Inc. v. Savencia, S.A.</i> , 2020 WL 5369076 (D. Del. Sept. 8, 2020)	3
<i>EMC Corp. v. Pure Storage, Inc.</i> , 2016 WL775742 (D. Del. Feb. 25, 2016)	3
<i>Intuitive Surgical, Inc. v. Auris Health, Inc.</i> , 549 F. Supp. 3d 362 (D. Del. 2021)	3
<i>IXYS Corp. v. Advanced Power Techs., Inc.</i> , 321 F. Supp. 2d 1133 (N.D. Cal 2004)	2
<i>SSL Servs., LLC v. Citrix Sys., Inc.</i> , 940 F. Supp. 2d 480 (E.D. Tex. 2013), <i>aff'd</i> , 769 F.3d 1073 (Fed. Cir. 2014)	3
<i>Steuben Foods, Inc. v. Shubiya Hoppmann Corp.</i> , 2021 WL 4775996 (D. Del. Oct. 13, 2021)	2
<i>Vehicular Techs. Corp. v. Titan Wheel Int'l</i> , 141 F.3d 1084 (Fed. Cir. 1998)	2

Magnolia’s overbroad request to preclude Kurin from doing what Magnolia itself openly plans to do—offering evidence or argument in Phase 1 that compares the accused products to commercial or patent embodiments—should be denied.¹

First, on commercial embodiments, Magnolia’s expert, Dr. Santiago, uses comparisons of the Kurin Lock to Magnolia’s commercial embodiment to opine on infringement. *See, e.g.*, Ex. 1 at ¶¶ 260, 336, 355–356. Likewise, Magnolia’s Phase 1 Exhibit List contains at least 24 documents relating to the design of Steripath. Ex. 2 (*See, e.g.*, PTX-337–PTX-445). During the parties’ pretrial meet and confers Magnolia expressly stated an intent to discuss its products as part of an “invention story” in putting on its direct infringement case. To the extent Magnolia is permitted during Phase 1 to discuss the design or features of Steripath, including in the context of or in relation to the patents-in-suit, Kurin is entitled to adduce responsive evidence, including regarding differences between Steripath and the Kurin Lock.

Second, Magnolia’s request would improperly preclude Kurin’s expert Dr. Antonsson from comparing the Kurin Lock to embodiments disclosed in the ’001 patent when analyzing “diverter”. “Diverter” was construed to be a means-plus-function limitation. D.I. 74 at 6, 10–11. Thus, as matter of basic patent law Kurin

¹ Magnolia’s title, introduction and argument focuses exclusively on Phase 1 (infringement), but Magnolia then requests broader relief. Magnolia makes no argument that the comparisons are not relevant in Phase 2, *e.g.*, damages and willfulness. Any relief should therefore be limited to Phase 1.

and Dr. Antonsson **must** discuss the disclosed embodiments of the '001 Patent and compare them to the accused device. *Id.* at 4 (citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347 (Fed. Cir. 2015)). Similarly, Dr. Antonsson's ¶ 404 opinion regarding "vent" that Magnolia quotes is a doctrine-of-equivalents ("DOE") opinion focusing on whether the specific **function** disclosed for that claim element in the specification is performed by the Kurin device. Ex. 16.1 at ¶ 404. Such reference to the specification, including embodiments, is proper DOE analysis regarding claim scope. *Vehicular Techs. Corp. v. Titan Wheel Int'l*, 141 F.3d 1084, 1090–91 (Fed. Cir. 1998); *see also IXYS Corp. v. Advanced Power Techs., Inc.*, 321 F. Supp. 2d 1133, 1143 (N.D. Cal. 2004). Likewise, Dr. Antonsson's noninfringement opinions under reverse DOE require comparison of Kurin Lock's operation to the patent's disclosures in order to determine whether the Kurin Lock performs the same function in a substantially different way. *Steuben Foods, Inc. v. Shubiya Hoppmann Corp.*, 2021 WL 4775996, at *4 (D. Del. Oct. 13, 2021).

With respect to other limitations and noninfringement more broadly, Kurin is not going to argue the Kurin lock does not infringe simply because the Kurin Lock is different from commercial or the specifications' preferred embodiments. But Magnolia, rehashing failed Daubert arguments, seeks to preclude what the caselaw *does* allow—an expert's analysis of the plain and ordinary meaning of claim terms and reference to embodiments consistent with such meaning. *See* D.I. 294; D.I. 297;

Intuitive Surgical, Inc. v. Auris Health, Inc., 549 F. Supp. 3d 362, 368 (D. Del. 2021) (“[Experts] may rely on portions of a patent to note that the patent uses the terms consistent with their plain and ordinary meaning.”); *Apple, Inc. v. Samsung Elecs. Co.*, 2014 WL 660857, at 4–5 & n.4 (N.D. Cal. Feb. 20, 2014); *SSL Servs., LLC v. Citrix Sys., Inc.*, 940 F. Supp. 2d 480, 492 (E.D. Tex. 2013), *aff’d*, 769 F.3d 1073 (Fed. Cir. 2014). No Magnolia case supports such overbroad relief. For example, *EMC Corp. v. Pure Storage, Inc.*, 2016 WL775742, at *4 (D. Del. Feb. 25, 2016) makes clear that whether experts’ reference to embodiments is proper should be determined “on an objection by objection basis in the context of the trial.”

On “sequester” and “seal member”, the only other claim terms Magnolia addressed, Dr. Antonsson states his own understanding of the plain and ordinary meaning of the term and then discusses how the specification (among other evidence, including, *e.g.*, a Magnolia internal document) is consistent with his understanding. *See, e.g.*, Ex. 16.1 at ¶¶ 140, 284–85, 373–380; Ex. 3 at ¶ 387. This is proper. *SSL Servs.*, 940 F. Supp. 2d at 492. Dr. Antonsson’s analysis is similarly proper for claim terms addressed in the remaining paragraphs Magnolia cites to without any explanation of how they are allegedly improper.²

For the foregoing reasons, the Court should deny Magnolia’s motion *in limine*.

² *ECB USA, Inc. v. Savencia, S.A.*, 2020 WL 5369076, at *4 (D. Del. Sept. 8, 2020) (“courts only decide issues that are fairly and fully presented.”).

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
kraman@paulweiss.com
jreich@paulweiss.com
abarel@paulweiss.com

RICHARDS, LAYTON & FINGER,
P.A.

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

May 27, 2022

2. Attached hereto as **Exhibit 2** is a true and correct copy of an excerpt from Magnolia's Trial Exhibit List, served May 20, 2022.

3. Attached hereto as **Exhibit 3** is a true and correct copy of an excerpt of the Rebuttal Expert Report of Erik K. Antonsson, dated February 18, 2021.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on May 27, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 19-00097-CFC

CONFIDENTIAL

OPENING EXPERT REPORT OF DR. JUAN G. SANTIAGO
REGARDING INFRINGEMENT OF U.S. PATENT NOS. 9,855,001
AND 10,039,483

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

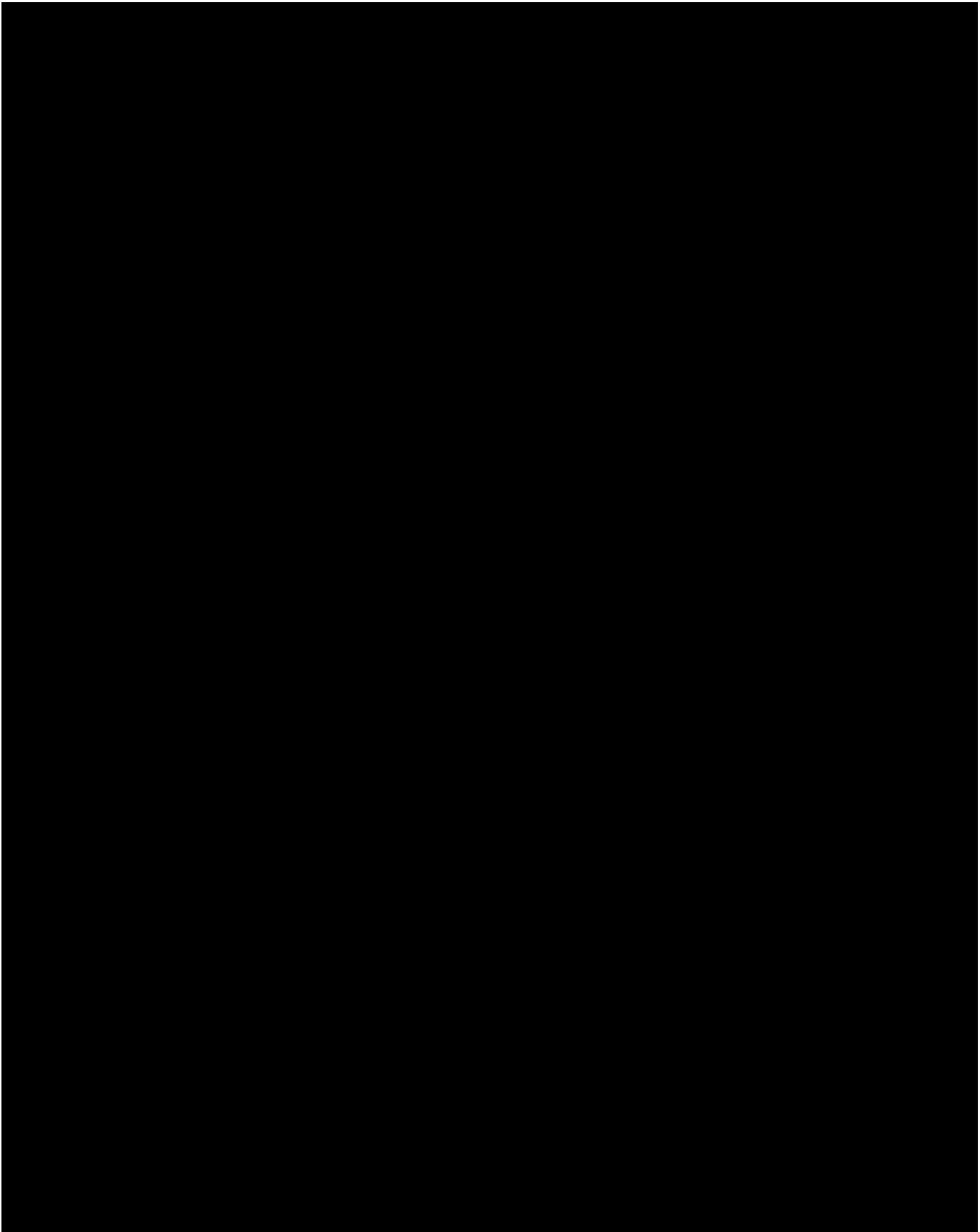
[REDACTED]

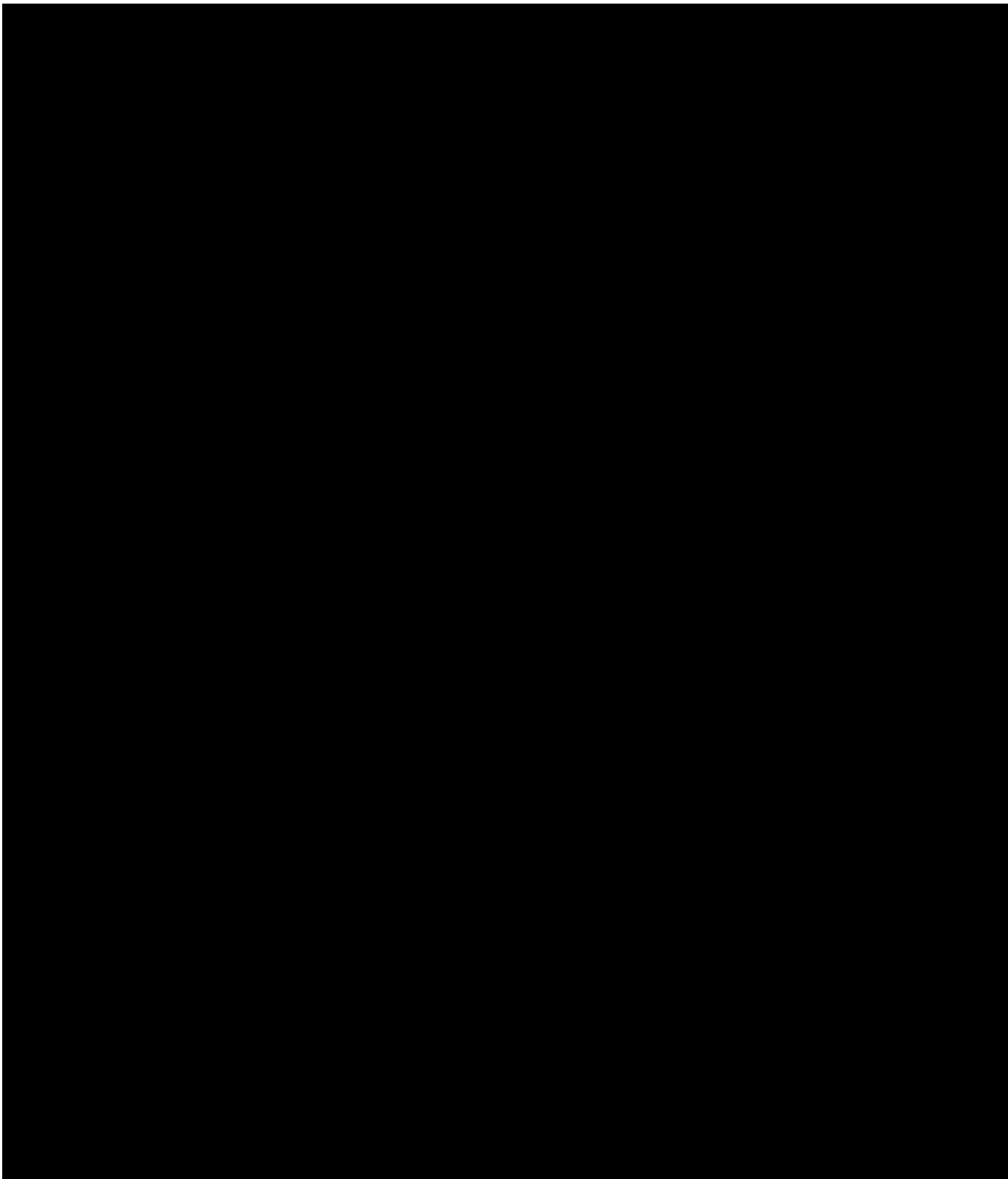
[REDACTED]

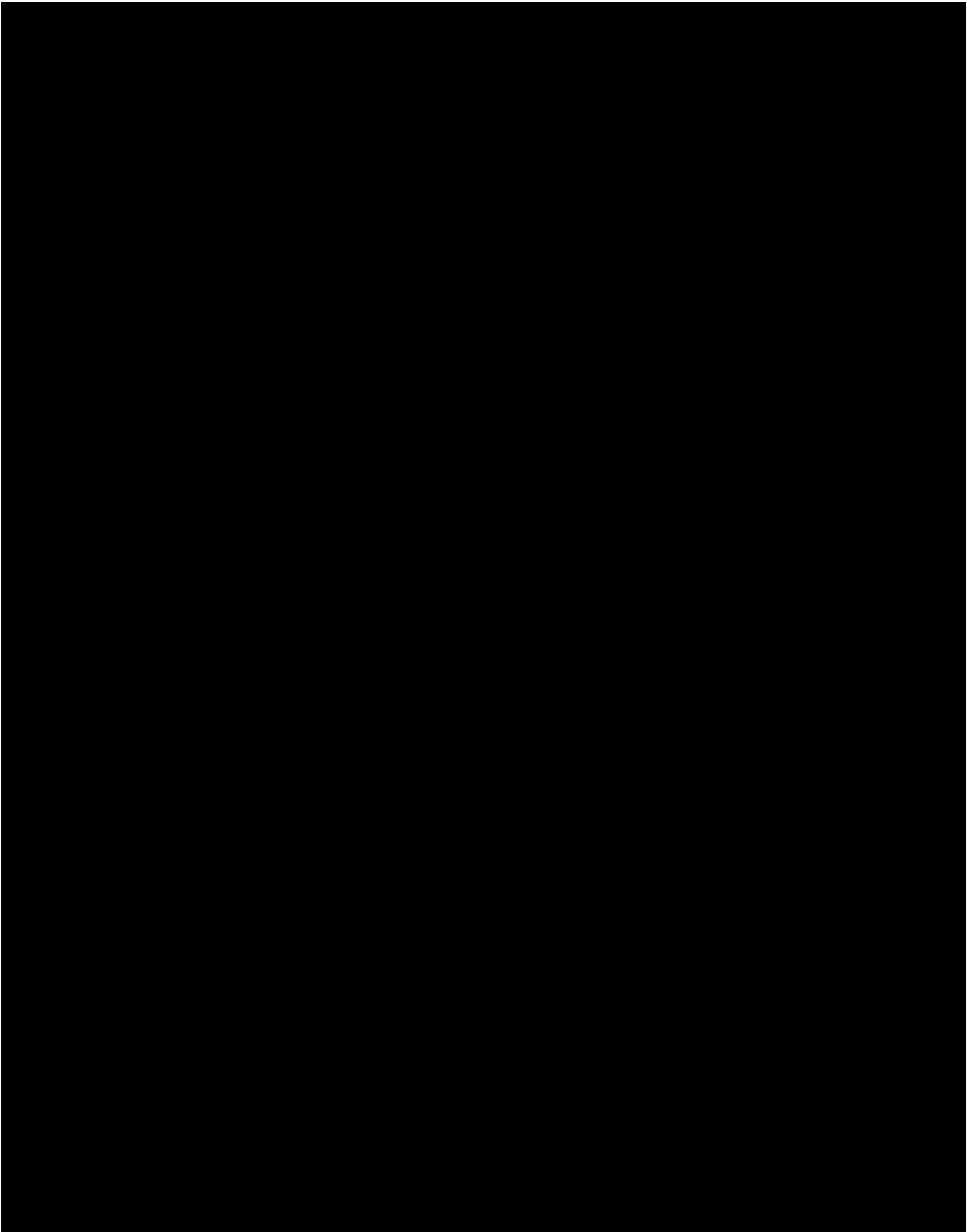
[REDACTED]

[REDACTED]

[REDACTED]







[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

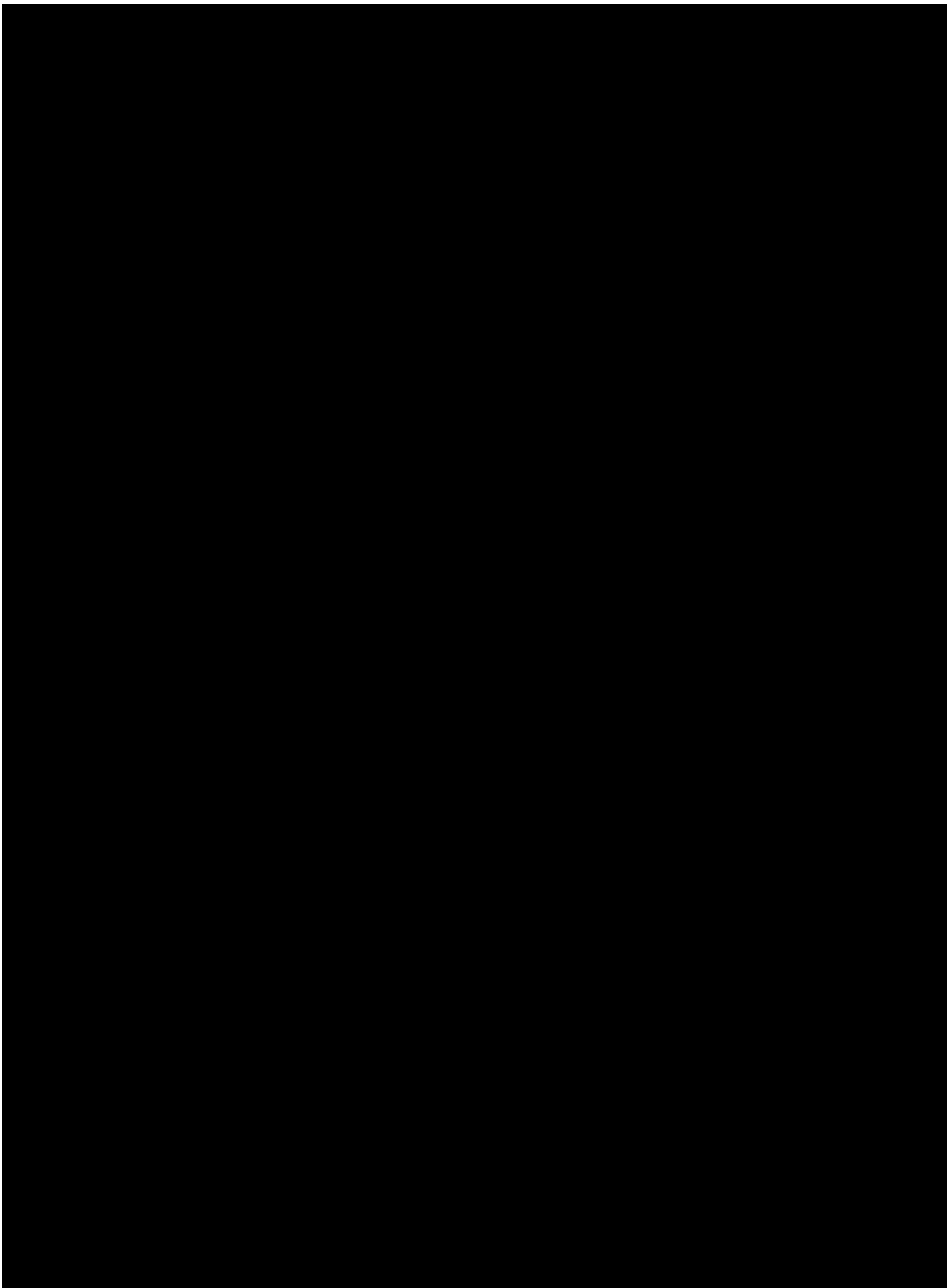
[REDACTED]

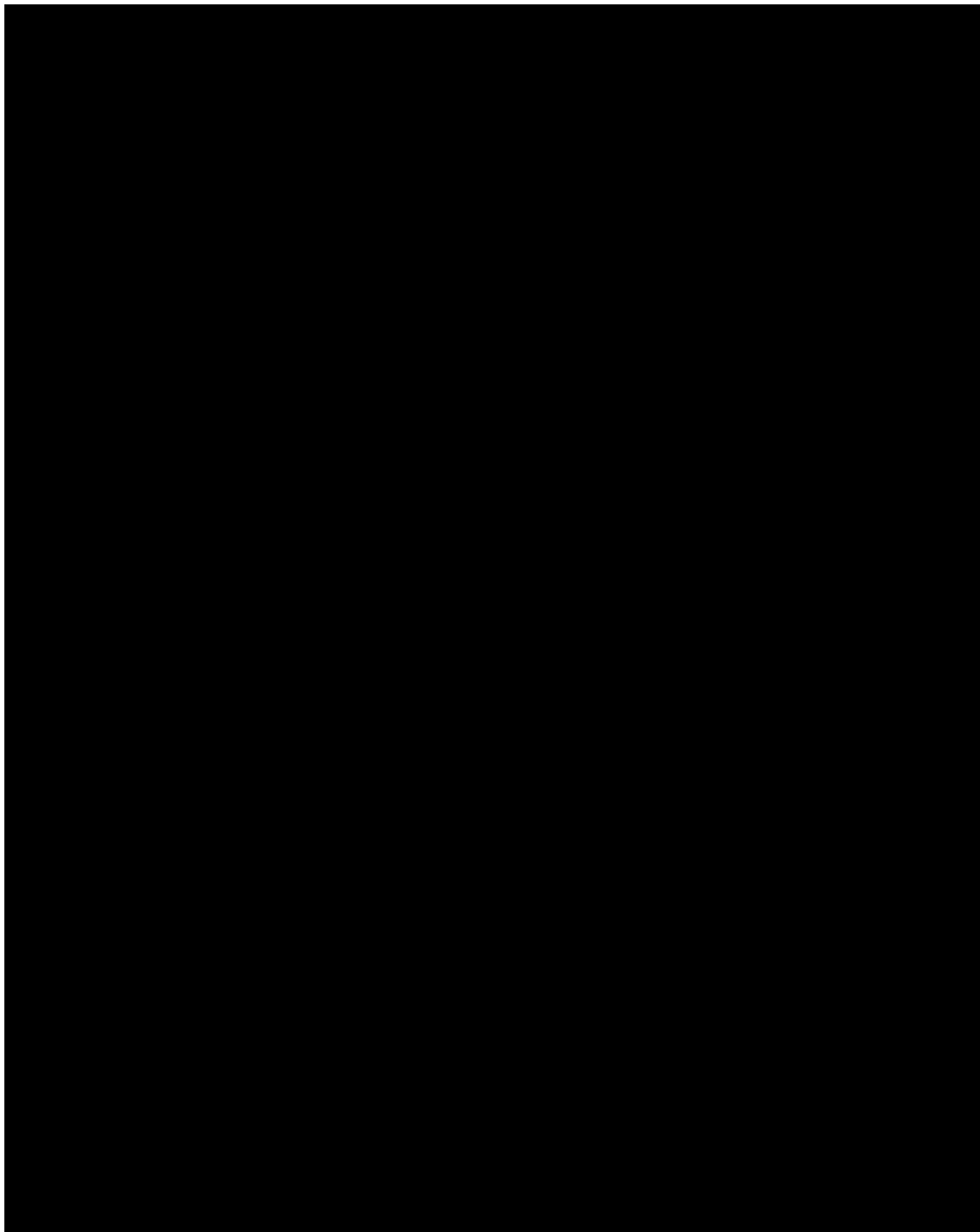
[REDACTED]

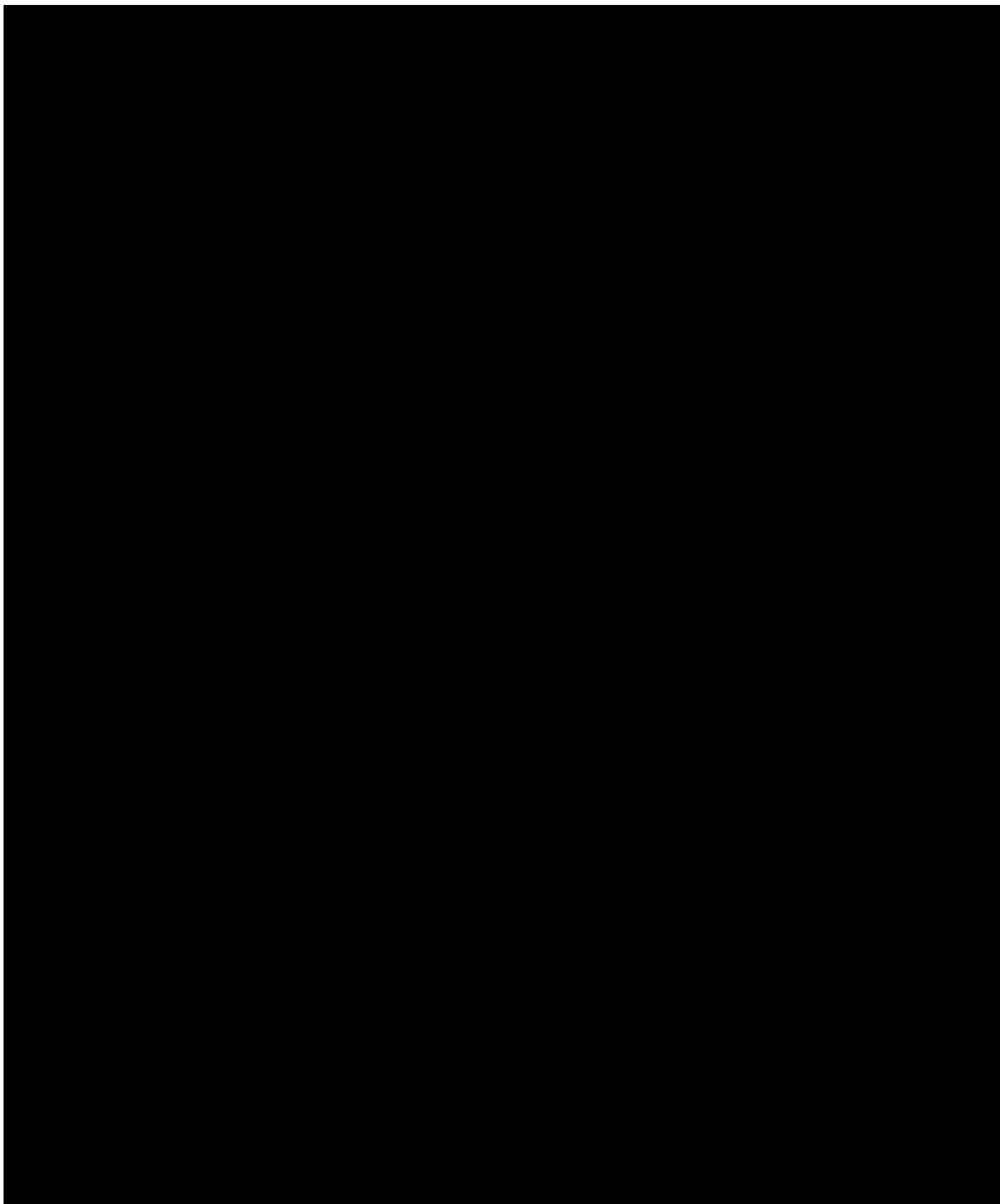
[REDACTED]

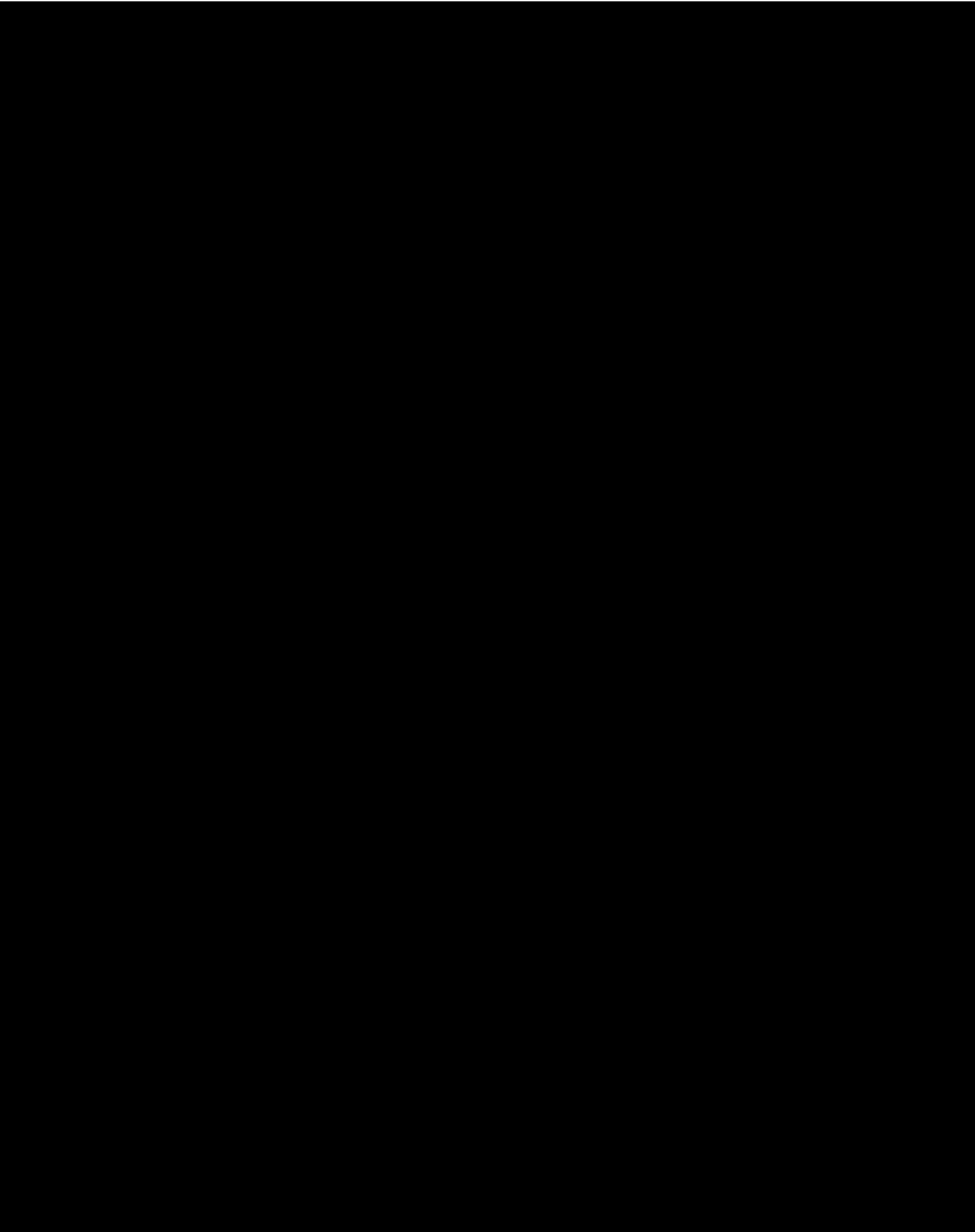
[REDACTED]

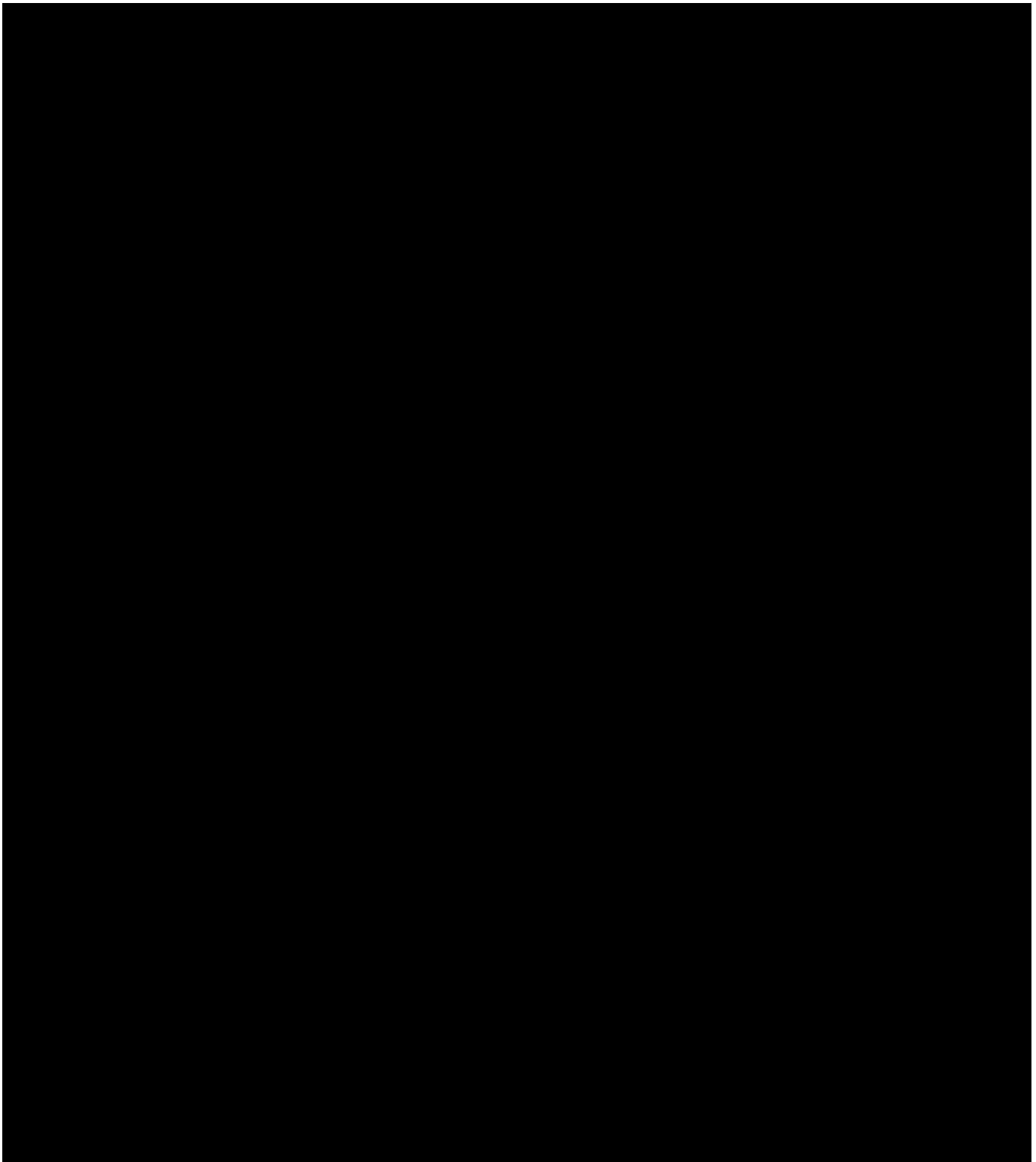
[REDACTED]











Respectfully submitted,

Dated: January 15, 2021

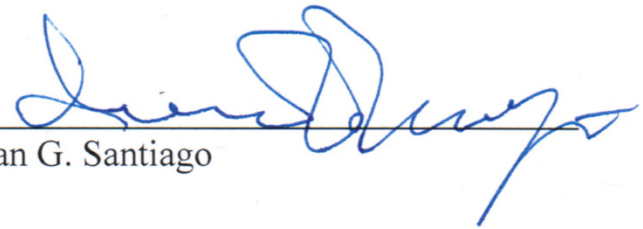

/s/ _____
Juan G. Santiago

EXHIBIT 2

TRIAL EX.	PHASE 1*	DESCRIPTION	BEG DATES	END DATES	DEPO EXS	KURIN'S OBJECTIONS
PTX-0299	Yes	Kurin Blood Culture Collection Set - PIV M-PIV12				
PTX-0300	Yes	Kurin Blood Culture Collection Set - PIV 18 Ref M-PIV18				
PTX-0301	Yes	Kurin Blood Culture Collection Set - S-PIV4				
PTX-0302	Yes	Kurin Blood Culture Collection Set - S-PIV10				
PTX-0303	Yes	Kurin T-11223				
PTX-0304	Yes	Prosecution history of U.S. Provisional Patent Application No. 61/546,954 entitled, "U.S. Patent Application Publication No. 13/650,554 entitled, "Fluid Diversion Mechanism for	MAG-DEL0002870	MAG-DEL0002885		402, 403, 602
PTX-0305	Yes	Prosecution history of U.S. Provisional Patent Application No. 60/870,599 entitled, "System	MAG-DEL0452590	MAG-DEL0452619		402, 403, 602
PTX-0306	Yes	Prosecution history of U.S. Patent Application No. 11/955,635 entitled, "Systems and	MAG-DEL0002846	MAG-DEL0002869		402, 403, 602
PTX-0307	Yes	Prosecution history of U.S. Patent Application No. 11/955,635 entitled, "Systems and	N/A	N/A		402, 403, 602
PTX-0309	Yes	Presentation entitled, "concept Exploration."	GAW0001976	GAW0001983		402, 403, 602
PTX-0314		Email from M. Heindel to J. Kelly, re: Kurin.com v2 - Updated site with MH's edits	KUR-MAG-DE119842	KUR-MAG-DE119849	Kelly 09	402, 403, 602, 802, 805, MIL
PTX-0315	Yes	Document entitled, "Kurin - Reshaping Blood Collection."	KUR-MAG-DE295232	KUR-MAG-DE295235	Heindel 33	402, 403, 602, 802, 805
PTX-0316		Email from C. Covington to M. Heindel re: "Updated - Bus Plan" Att: business pan dec 2016_r2.docx	KUR-MAG-DE477524 KUR-MAG-DE477525	KUR-MAG-DE477524 KUR-MAG-DE477538	Covington 17 Heindel 11	402, 403, 602, 802, 805, MIL
PTX-0318		Presentation entitled, "Kurin Training"	KUR-MAG-DE043872	KUR-MAG-DE043893	Covington 12 Heindel 23 Lloyd 09	402, 403, 602, 802, 805, MIL
PTX-0319	Yes	Presentation entitled, "Establishing the New Standard-of-Care Enabling Sepsis Testing	MAG-DEL0013467	MAG-DEL0013475		402, 403, 602, 802, 805
PTX-0320	Yes	Brochure entitled, "Kurin Blood Culture Collection Sets"	KUR-MAG-DE003008	KUR-MAG-DE003009	Kelly 22	402, 403, 602, 802, 805, MIL
PTX-0323	Yes	Email from D. Lloyd to C. Covington, M. Heindel, and A. Norfleet, re: Rep PP FOR VEGAS and Matt H Atts: Sales Cycle_NSM 1_4_2019.pptx; 2019 Jan Poole KDMC Presentation.pptx; Tom Price Geisinger Holy Spirit presentation 2.pptx; 2019 Noble Vegas .pptx; HPG MAC JONES.1-2019.pptx; 2019 sales meeting BOB JENEY v2 sales funnel.pptx; VEGAS HEINDELJan 2019.pptx	KUR-MAG-DE003042 KUR-MAG-DE003043 KUR-MAG-DE003044 KUR-MAG-DE003049 KUR-MAG-DE003050 KUR-MAG-DE003056 KUR-MAG-DE003057 KUR-MAG-DE003062 KUR-MAG-DE003063 KUR-MAG-DE003066 KUR-MAG-DE003067 KUR-MAG-DE003072 KUR-MAG-DE003073 KUR-MAG-DE003074 KUR-MAG-DE003081 KUR-MAG-DE003082 KUR-MAG-DE003083 KUR-MAG-DE003084 KUR-MAG-DE003085 KUR-MAG-DE003086 KUR-MAG-DE003087 KUR-MAG-DE003088 KUR-MAG-DE003089 KUR-MAG-DE003090 KUR-MAG-DE003091 KUR-MAG-DE003092 KUR-MAG-DE003093 KUR-MAG-DE003094 KUR-MAG-DE003095 KUR-MAG-DE003096 KUR-MAG-DE003097 KUR-MAG-DE003098 KUR-MAG-DE003099 KUR-MAG-DE003100 KUR-MAG-DE003101 KUR-MAG-DE003102 KUR-MAG-DE003103 KUR-MAG-DE003104 KUR-MAG-DE003105 KUR-MAG-DE003106 KUR-MAG-DE003107 KUR-MAG-DE003108 KUR-MAG-DE003109 KUR-MAG-DE003110 KUR-MAG-DE003111 KUR-MAG-DE003112 KUR-MAG-DE003113 KUR-MAG-DE003114 KUR-MAG-DE003115 KUR-MAG-DE003116 KUR-MAG-DE003117 KUR-MAG-DE003118 KUR-MAG-DE003119 KUR-MAG-DE003120 KUR-MAG-DE003121 KUR-MAG-DE003122 KUR-MAG-DE003123 KUR-MAG-DE003124 KUR-MAG-DE003125 KUR-MAG-DE003126 KUR-MAG-DE003127 KUR-MAG-DE003128 KUR-MAG-DE003129 KUR-MAG-DE003130 KUR-MAG-DE003131 KUR-MAG-DE003132 KUR-MAG-DE003133 KUR-MAG-DE003134 KUR-MAG-DE003135 KUR-MAG-DE003136 KUR-MAG-DE003137 KUR-MAG-DE003138 KUR-MAG-DE003139 KUR-MAG-DE003140 KUR-MAG-DE003141 KUR-MAG-DE003142 KUR-MAG-DE003143 KUR-MAG-DE003144 KUR-MAG-DE003145 KUR-MAG-DE003146 KUR-MAG-DE003147 KUR-MAG-DE003148 KUR-MAG-DE003149 KUR-MAG-DE003150 KUR-MAG-DE003151 KUR-MAG-DE003152 KUR-MAG-DE003153 KUR-MAG-DE003154 KUR-MAG-DE003155 KUR-MAG-DE003156 KUR-MAG-DE003157 KUR-MAG-DE003158 KUR-MAG-DE003159 KUR-MAG-DE003160 KUR-MAG-DE003161 KUR-MAG-DE003162 KUR-MAG-DE003163 KUR-MAG-DE003164 KUR-MAG-DE003165 KUR-MAG-DE003166 KUR-MAG-DE003167 KUR-MAG-DE003168 KUR-MAG-DE003169 KUR-MAG-DE003170 KUR-MAG-DE003171 KUR-MAG-DE003172 KUR-MAG-DE003173 KUR-MAG-DE003174 KUR-MAG-DE003175 KUR-MAG-DE003176 KUR-MAG-DE003177 KUR-MAG-DE003178 KUR-MAG-DE003179 KUR-MAG-DE003180 KUR-MAG-DE003181 KUR-MAG-DE003182 KUR-MAG-DE003183 KUR-MAG-DE003184 KUR-MAG-DE003185 KUR-MAG-DE003186 KUR-MAG-DE003187 KUR-MAG-DE003188 KUR-MAG-DE003189 KUR-MAG-DE003190 KUR-MAG-DE003191 KUR-MAG-DE003192 KUR-MAG-DE003193 KUR-MAG-DE003194 KUR-MAG-DE003195 KUR-MAG-DE003196 KUR-MAG-DE003197 KUR-MAG-DE003198 KUR-MAG-DE003199 KUR-MAG-DE003200 KUR-MAG-DE003201 KUR-MAG-DE003202 KUR-MAG-DE003203 KUR-MAG-DE003204 KUR-MAG-DE003205 KUR-MAG-DE003206 KUR-MAG-DE003207 KUR-MAG-DE003208 KUR-MAG-DE003209 KUR-MAG-DE003210 KUR-MAG-DE003211 KUR-MAG-DE003212 KUR-MAG-DE003213 KUR-MAG-DE003214 KUR-MAG-DE003215 KUR-MAG-DE003216 KUR-MAG-DE003217 KUR-MAG-DE003218 KUR-MAG-DE003219 KUR-MAG-DE003220 KUR-MAG-DE003221 KUR-MAG-DE003222 KUR-MAG-DE003223 KUR-MAG-DE003224 KUR-MAG-DE003225 KUR-MAG-DE003226 KUR-MAG-DE003227 KUR-MAG-DE003228 KUR-MAG-DE003229 KUR-MAG-DE003230 KUR-MAG-DE003231 KUR-MAG-DE003232 KUR-MAG-DE003233 KUR-MAG-DE003234 KUR-MAG-DE003235 KUR-MAG-DE003236 KUR-MAG-DE003237 KUR-MAG-DE003238 KUR-MAG-DE003239 KUR-MAG-DE003240 KUR-MAG-DE003241 KUR-MAG-DE003242 KUR-MAG-DE003243 KUR-MAG-DE003244 KUR-MAG-DE003245 KUR-MAG-DE003246 KUR-MAG-DE003247 KUR-MAG-DE003248 KUR-MAG-DE003249 KUR-MAG-DE003250 KUR-MAG-DE003251 KUR-MAG-DE003252 KUR-MAG-DE003253 KUR-MAG-DE003254 KUR-MAG-DE003255 KUR-MAG-DE003256 KUR-MAG-DE003257 KUR-MAG-DE003258 KUR-MAG-DE003259 KUR-MAG-DE003260 KUR-MAG-DE003261 KUR-MAG-DE003262 KUR-MAG-DE003263 KUR-MAG-DE003264 KUR-MAG-DE003265 KUR-MAG-DE003266 KUR-MAG-DE003267 KUR-MAG-DE003268 KUR-MAG-DE003269 KUR-MAG-DE003270 KUR-MAG-DE003271 KUR-MAG-DE003272 KUR-MAG-DE003273 KUR-MAG-DE003274 KUR-MAG-DE003275 KUR-MAG-DE003276 KUR-MAG-DE003277 KUR-MAG-DE003278 KUR-MAG-DE003279 KUR-MAG-DE003280 KUR-MAG-DE003281 KUR-MAG-DE003282 KUR-MAG-DE003283 KUR-MAG-DE003284 KUR-MAG-DE003285 KUR-MAG-DE003286 KUR-MAG-DE003287 KUR-MAG-DE003288 KUR-MAG-DE003289 KUR-MAG-DE003290 KUR-MAG-DE003291 KUR-MAG-DE003292 KUR-MAG-DE003293 KUR-MAG-DE003294 KUR-MAG-DE003295 KUR-MAG-DE003296 KUR-MAG-DE003297 KUR-MAG-DE003298 KUR-MAG-DE003299 KUR-MAG-DE003300 KUR-MAG-DE003301 KUR-MAG-DE003302 KUR-MAG-DE003303 KUR-MAG-DE003304 KUR-MAG-DE003305 KUR-MAG-DE003306 KUR-MAG-DE003307 KUR-MAG-DE003308 KUR-MAG-DE003309 KUR-MAG-DE003310 KUR-MAG-DE003311 KUR-MAG-DE003312 KUR-MAG-DE003313 KUR-MAG-DE003314 KUR-MAG-DE003315 KUR-MAG-DE003316 KUR-MAG-DE003317 KUR-MAG-DE003318 KUR-MAG-DE003319 KUR-MAG-DE003320 KUR-MAG-DE003321 KUR-MAG-DE003322 KUR-MAG-DE003323 KUR-MAG-DE003324 KUR-MAG-DE003325 KUR-MAG-DE003326 KUR-MAG-DE003327 KUR-MAG-DE003328 KUR-MAG-DE003329 KUR-MAG-DE003330 KUR-MAG-DE003331 KUR-MAG-DE003332 KUR-MAG-DE003333 KUR-MAG-DE003334 KUR-MAG-DE003335 KUR-MAG-DE003336 KUR-MAG-DE003337 KUR-MAG-DE003338 KUR-MAG-DE003339 KUR-MAG-DE003340 KUR-MAG-DE003341 KUR-MAG-DE003342 KUR-MAG-DE003343 KUR-MAG-DE003344 KUR-MAG-DE003345 KUR-MAG-DE003346 KUR-MAG-DE003347 KUR-MAG-DE003348 KUR-MAG-DE003349 KUR-MAG-DE003350 KUR-MAG-DE003351 KUR-MAG-DE003352 KUR-MAG-DE003353 KUR-MAG-DE003354 KUR-MAG-DE003355 KUR-MAG-DE003356 KUR-MAG-DE003357 KUR-MAG-DE003358 KUR-MAG-DE003359 KUR-MAG-DE003360 KUR-MAG-DE003361 KUR-MAG-DE003362 KUR-MAG-DE003363 KUR-MAG-DE003364 KUR-MAG-DE003365 KUR-MAG-DE003366 KUR-MAG-DE003367 KUR-MAG-DE003368 KUR-MAG-DE003369 KUR-MAG-DE003370 KUR-MAG-DE003371 KUR-MAG-DE003372 KUR-MAG-DE003373 KUR-MAG-DE003374 KUR-MAG-DE003375 KUR-MAG-DE003376 KUR-MAG-DE003377 KUR-MAG-DE003378 KUR-MAG-DE003379 KUR-MAG-DE003380 KUR-MAG-DE003381 KUR-MAG-DE003382 KUR-MAG-DE003383 KUR-MAG-DE003384 KUR-MAG-DE003385 KUR-MAG-DE003386 KUR-MAG-DE003387 KUR-MAG-DE003388 KUR-MAG-DE003389 KUR-MAG-DE003390 KUR-MAG-DE003391 KUR-MAG-DE003392 KUR-MAG-DE003393 KUR-MAG-DE003394 KUR-MAG-DE003395 KUR-MAG-DE003396 KUR-MAG-DE003397 KUR-MAG-DE003398 KUR-MAG-DE003399 KUR-MAG-DE003400 KUR-MAG-DE003401 KUR-MAG-DE003402 KUR-MAG-DE003403 KUR-MAG-DE003404 KUR-MAG-DE003405 KUR-MAG-DE003406 KUR-MAG-DE003407 KUR-MAG-DE003408 KUR-MAG-DE003409 KUR-MAG-DE003410 KUR-MAG-DE003411 KUR-MAG-DE003412 KUR-MAG-DE003413 KUR-MAG-DE003414 KUR-MAG-DE003415 KUR-MAG-DE003416 KUR-MAG-DE003417 KUR-MAG-DE003418 KUR-MAG-DE003419 KUR-MAG-DE003420 KUR-MAG-DE003421 KUR-MAG-DE003422 KUR-MAG-DE003423 KUR-MAG-DE003424 KUR-MAG-DE003425 KUR-MAG-DE003426 KUR-MAG-DE003427 KUR-MAG-DE003428 KUR-MAG-DE003429 KUR-MAG-DE003430 KUR-MAG-DE003431 KUR-MAG-DE003432 KUR-MAG-DE003433 KUR-MAG-DE003434 KUR-MAG-DE003435 KUR-MAG-DE003436 KUR-MAG-DE003437 KUR-MAG-DE003438 KUR-MAG-DE003439 KUR-MAG-DE003440 KUR-MAG-DE003441 KUR-MAG-DE003442 KUR-MAG-DE003443 KUR-MAG-DE003444 KUR-MAG-DE003445 KUR-MAG-DE003446 KUR-MAG-DE003447 KUR-MAG-DE003448 KUR-MAG-DE003449 KUR-MAG-DE003450 KUR-MAG-DE003451 KUR-MAG-DE003452 KUR-MAG-DE003453 KUR-MAG-DE003454 KUR-MAG-DE003455 KUR-MAG-DE003456 KUR-MAG-DE003457 KUR-MAG-DE003458 KUR-MAG-DE003459 KUR-MAG-DE003460 KUR-MAG-DE003461 KUR-MAG-DE003462 KUR-MAG-DE003463 KUR-MAG-DE003464 KUR-MAG-DE003465 KUR-MAG-DE003466 KUR-MAG-DE003467 KUR-MAG-DE003468 KUR-MAG-DE003469 KUR-MAG-DE003470 KUR-MAG-DE003471 KUR-MAG-DE003472 KUR-MAG-DE003473 KUR-MAG-DE003474 KUR-MAG-DE003475 KUR-MAG-DE003476 KUR-MAG-DE003477 KUR-MAG-DE003478 KUR-MAG-DE003479 KUR-MAG-DE003480 KUR-MAG-DE003481 KUR-MAG-DE003482 KUR-MAG-DE003483 KUR-MAG-DE003484 KUR-MAG-DE003485 KUR-MAG-DE003486 KUR-MAG-DE003487 KUR-MAG-DE003488 KUR-MAG-DE003489 KUR-MAG-DE003490 KUR-MAG-DE003491 KUR-MAG-DE003492 KUR-MAG-DE003493 KUR-MAG-DE003494 KUR-MAG-DE003495 KUR-MAG-DE003496 KUR-MAG-DE003497 KUR-MAG-DE003498 KUR-MAG-DE003499 KUR-MAG-DE003500 KUR-MAG-DE003501 KUR-MAG-DE003502 KUR-MAG-DE003503 KUR-MAG-DE003504 KUR-MAG-DE003505 KUR-MAG-DE003506 KUR-MAG-DE003507 KUR-MAG-DE003508 KUR-MAG-DE003509 KUR-MAG-DE003510 KUR-MAG-DE003511 KUR-MAG-DE003512 KUR-MAG-DE003513 KUR-MAG-DE003514 KUR-MAG-DE003515 KUR-MAG-DE003516 KUR-MAG-DE003517 KUR-MAG-DE003518 KUR-MAG-DE003519 KUR-MAG-DE003520 KUR-MAG-DE003521 KUR-MAG-DE003522 KUR-MAG-DE003523 KUR-MAG-DE003524 KUR-MAG-DE003525 KUR-MAG-DE003526 KUR-MAG-DE003527 KUR-MAG-DE003528 KUR-MAG-DE003529 KUR-MAG-DE003530 KUR-MAG-DE003531 KUR-MAG-DE003532 KUR-MAG-DE003533 KUR-MAG-DE003534 KUR-MAG-DE003535 KUR-MAG-DE003536 KUR-MAG-DE003537 KUR-MAG-DE003538 KUR-MAG-DE003539 KUR-MAG-DE003540 KUR-MAG-DE003541 KUR-MAG-DE003542 KUR-MAG-DE003543 KUR-MAG-DE003544 KUR-MAG-DE003545 KUR-MAG-DE003546 KUR-MAG-DE003547 KUR-MAG-DE003548 KUR-MAG-DE003549 KUR-MAG-DE003550 KUR-MAG-DE003551 KUR-MAG-DE003552 KUR-MAG-DE003553 KUR-MAG-DE003554 KUR-MAG-DE003555 KUR-MAG-DE003556 KUR-MAG-DE003557 KUR-MAG-DE003558 KUR-MAG-DE003559 KUR-MAG-DE003560 KUR-MAG-DE003561 KUR-MAG-DE003562 KUR-MAG-DE003563 KUR-MAG-DE003564 KUR-MAG-DE003565 KUR-MAG-DE003566 KUR-MAG-DE003567 KUR-MAG-DE003568 KUR-MAG-DE003569 KUR-MAG-DE003570 KUR-MAG-DE003571 KUR-MAG-DE003572 KUR-MAG-DE003573 KUR-MAG-DE003574 KUR-MAG-DE003575 KUR-MAG-DE003576 KUR-MAG-DE003577 KUR-MAG-DE003578 KUR-MAG-DE003579 KUR-MAG-DE003580 KUR-MAG-DE003581 KUR-MAG-DE003582 KUR-MAG-DE003583 KUR-MAG-DE003584 KUR-MAG-DE003585 KUR-MAG-DE003586 KUR-MAG-DE003587 KUR-MAG-DE003588 KUR-MAG-DE003589 KUR-MAG-DE003590 KUR-MAG-DE003591 KUR-MAG-DE003592 KUR-MAG-DE003593 KUR-MAG-DE003594 KUR-MAG-DE003595 KUR-MAG-DE003596 KUR-MAG-DE003597 KUR-MAG-DE003598 KUR-MAG-DE003599 KUR-MAG-DE003600 KUR-MAG-DE003601 KUR-MAG-DE003602 KUR-MAG-DE003603 KUR-MAG-DE003604 KUR-MAG-DE003605 KUR-MAG-DE003606 KUR-MAG-DE003607 KUR-MAG-DE003608 KUR-MAG-DE003609 KUR-MAG-DE003610 KUR-MAG-DE003611 KUR-MAG-DE003612 KUR-MAG-DE003613 KUR-MAG-DE003614 KUR-MAG-DE003615 KUR-MAG-DE003616 KUR-MAG-DE003617 KUR-MAG-DE003618 KUR-MAG-DE003619 KUR-MAG-DE003620 KUR-MAG-DE003621 KUR-MAG-DE003622 KUR-MAG-DE003623 KUR-MAG-DE003624 KUR-MAG-DE003625 KUR-MAG-DE003626 KUR-MAG-DE003627 KUR-MAG-DE003628 KUR-MAG-DE003629 KUR-MAG-DE003630 KUR-MAG-DE003631 KUR-MAG-DE003632 KUR-MAG-DE003633 KUR-MAG-DE003634 KUR-MAG-DE003635 KUR-MAG-DE003636 KUR-MAG-DE003637 KUR-MAG-DE003638 KUR-MAG-DE003639 KUR-MAG-DE003640 KUR-MAG-DE003641 KUR-MAG-DE003642 KUR-MAG-DE003643 KUR-MAG-DE003644 KUR-MAG-DE003645 KUR-MAG-DE003646 KUR-MAG-DE003647 KUR-MAG-DE003648 KUR-MAG-DE003649 KUR-MAG-DE003650 KUR-MAG-DE003651 KUR-MAG-DE003652 KUR-MAG-DE003653 KUR-MAG-DE003654 KUR-MAG-DE003655 KUR-MAG-DE003656 KUR-MAG-DE003657 KUR-MAG-DE003658 KUR-MAG-DE003659 KUR-MAG-DE003660 KUR-MAG-DE003661 KUR-MAG-DE003662 KUR-MAG-DE003663 KUR-MAG-DE003664 KUR-MAG-DE003665 KUR-MAG-DE003666 KUR-MAG-DE003667 KUR-MAG-DE003668 KUR-MAG-DE003669 KUR-MAG-DE003670 KUR-MAG-DE003671 KUR-MAG-DE003672 KUR-MAG-DE003673 KUR-MAG-DE003674 KUR-MAG-DE003675 KUR-MAG-DE003676 KUR-MAG-DE003677 KUR-MAG-DE003678 KUR-MAG-DE003679 KUR-MAG-DE003680 KUR-MAG-DE003681 KUR-MAG-DE003682 KUR-MAG-DE003683 KUR-MAG-DE003684 KUR-MAG-DE003685 KUR-MAG-DE003686 KUR-MAG-DE003687 KUR-MAG-DE003688 KUR-MAG-DE003689 KUR-MAG-DE003690 KUR-MAG-DE003691 KUR-MAG-DE003692 KUR-MAG-DE003693 KUR-MAG-DE003694 KUR-MAG-DE003695 KUR-MAG-DE003696 KUR-MAG-DE003697 KUR-MAG-DE003698 KUR-MAG-DE003699 KUR-MAG-DE003700 KUR-MAG-DE003701 KUR-MAG-DE003702 KUR-MAG-DE003703 KUR-MAG-DE003704 KUR-MAG-DE003705 KUR-MAG-DE003706 KUR-MAG-DE003707 KUR-MAG-DE003708 KUR-MAG-DE003709 KUR-MAG-DE003710 KUR-MAG-DE003711 KUR-MAG-DE003712 KUR-MAG-DE003713 KUR-MAG-DE003714 KUR-MAG-DE003715 KUR-MAG-DE003716 KUR-MAG-DE003717 KUR-MAG-DE003718 KUR-MAG-DE003719 KUR-MAG-DE003720 KUR-MAG-DE003721 KUR-MAG-DE003722 KUR-MAG-DE003723 KUR-MAG-DE003724 KUR-MAG-DE003725 KUR-MAG-DE003726 KUR-MAG-DE003727 KUR-MAG-DE003728 KUR-MAG-DE003729 KUR-MAG-DE003730 KUR-MAG-DE003731 KUR-MAG-DE003732 KUR-MAG-DE003733 KUR-MAG-DE003734 KUR-MAG-DE003735 KUR-MAG-DE003736 KUR-MAG-DE003737 KUR-MAG-DE003738 KUR-MAG-DE003739 KUR-MAG-DE003740 KUR-MAG-DE003741 KUR-MAG-DE003742 KUR-MAG-DE003743 KUR-MAG-DE003744 KUR-MAG-DE003745 KUR-MAG-DE003746 KUR-MAG-DE003747 KUR-MAG-DE003748 KUR-MAG-DE003749 KUR-MAG-DE003750 KUR-MAG-DE003751 KUR-MAG-DE003752 KUR-MAG-DE003753 KUR-MAG-DE003754 KUR-MAG-DE003755 KUR-MAG-DE003756 KUR-MAG-DE003757 KUR-MAG-DE003758 KUR-MAG-DE003759 KUR-MAG-DE003760 KUR-MAG-DE003761 KUR-MAG-DE003762 KUR-MAG-DE003763 KUR-MAG-DE003764 KUR-MAG-DE003765 KUR-MAG-DE003766 KUR-MAG-DE003767 KUR-MAG-DE003768 KUR-MAG-DE003769 KUR-MAG-DE003770 KUR-MAG-DE003771 KUR-MAG-DE003772 KUR-MAG-DE003773 KUR-MAG-DE003774 KUR-MAG-DE003775 KUR-MAG-DE003776 KUR-MAG-DE003777 KUR-MAG-DE003778 KUR-MAG-DE003779 KUR-MAG-DE003780 KUR-MAG-DE003781 KUR-MAG-DE003782 KUR-MAG-DE003783 KUR-MAG-DE003784 KUR-MAG-DE003785 KUR-MAG-DE003786 KUR-MAG-DE003787 KUR-MAG-DE003788 KUR-MAG-DE003789 KUR-MAG-DE003790 KUR-MAG-DE003791 KUR-MAG-DE003792 KUR-MAG-DE003793 KUR-MAG-DE003794 KUR-MAG-DE003795 KUR-MAG-DE003796 KUR-MAG-DE003797 KUR-MAG-DE003798 KUR-MAG-DE003799 KUR-MAG-DE003800 KUR-MAG-DE003801 KUR-MAG-DE003802 KUR-MAG-DE003803 KUR-MAG-DE003804 KUR-MAG-DE003805 KUR-MAG-DE003806 KUR-MAG-DE003807 KUR-MAG-DE003808 KUR-MAG-DE003809 KUR-MAG-DE003810 KUR-MAG-DE003811 KUR-MAG-DE003812 KUR-MAG-DE003813 KUR-MAG-DE003814 KUR-MAG-DE003815 KUR-MAG-DE003816 KUR-MAG-DE003817 KUR-MAG-DE003818 KUR-MAG-DE003819 KUR-MAG-DE003820 KUR-MAG-DE003821 KUR-MAG-DE003822 KUR-MAG-DE003823 KUR-MAG-DE003824 KUR-MAG-DE003825			

* Magnolia provides the marking of evidence by phase herein in reliance on Kurin's May 10, 2022 email confirming that "Kurin will not argue that Magnolia's good-faith disclosures of evidence by phase are binding or preclusive."

TRIAL EX.	PHASE 1*	DESCRIPTION	BEG BATES	END BATES	DEPO EXS	KURIN'S OBJECTIONS
PTX-0342	Yes	Presentation entitled, "conceptexploration"	MAG-DEL0001037	MAG-DEL0001039		402, 403, 602, 802, 805
PTX-0343	Yes	Presentation entitled, "Final Concept Selection, Designs for Prototyping"	MAG-DEL0001241	MAG-DEL0001282	Gaw 08 (GAW0001990)	402, 403, 602, 802, 805
PTX-0347	Yes	Presentation entitled, "conceptexploration"	MAG-DEL0001040	MAG-DEL0001049		402, 403, 602, 802, 805
PTX-0350	Yes	Presentation entitled, "Concept"	MAG-DEL0001445	MAG-DEL0001453		402, 403, 602, 802
PTX-0351	Yes	Presentation entitled, "conceptexploration ISDT kit concepts"	MAG-DEL0001002	MAG-DEL0001008		402, 403, 602, 802
PTX-0352	Yes	Presentation entitled, "conceptexploration PDF"				
PTX-0353	Yes	Presentation entitled, "conceptexploration"	MAG-DEL0001009	MAG-DEL0001062		402, 403, 602, 802
PTX-0355	Yes	Presentation entitled, "conceptexploration"	MAG-DEL0001016	MAG-DEL0001015		402, 403, 602, 802
PTX-0356	Yes	Filename: MMT ISDT Program Schedule 041112a.pdf	MAG-DEL0001016	MAG-DEL0001022		402, 403, 602, 802
PTX-0358	Yes	Presentation entitled, "conceptexploration" concepts"	MAG-DEL0001023	MAG-DEL0001029		402, 403, 602, 802
PTX-0359	Yes	Document entitled, "Magnolia ISDT Initial Thoughts"	MAG-DEL0000872	MAG-DEL0000874		402, 403, 602, 802
PTX-0360	Yes	Email from G. Bullinton to K. Rice re: "User feedback on ergonomics/finger positioning"	MAG-DEL0000940	MAG-DEL0000941		402, 403, 602, 802
PTX-0437	Yes	8305al.jpg	GAW0000319	GAW0000319		402, 403, 602
PTX-0438	Yes	8306al.jpg	GAW0000320	GAW0000320		402, 403, 602
PTX-0439	Yes	8311al.jpg	GAW0000321	GAW0000321		402, 403, 602
PTX-0440	Yes	8315al.jpg	GAW0000322	GAW0000322		402, 403, 602
PTX-0442	Yes	8329al.jpg	GAW0000324	GAW0000324		402, 403, 602
PTX-0443	Yes	8336al.jpg	GAW0000325	GAW0000325		402, 403, 602
PTX-0444	Yes	8357al.jpg	GAW0000326	GAW0000326		402, 403, 602
PTX-0445	Yes	8374al.jpg	GAW0000327	GAW0000327		402, 403, 602
PTX-0464	Yes	Email from G. Bullington to J. Maruska re: "Logo / mark / font(s) / color palate" Att: MMT Proto Overview 120607.pdf	MAG-DEL0000916 MAG-DEL0000918	MAG-DEL0000917 MAG-DEL0000925		402, 403, 602, 802, 805
PTX-0466	Yes	Email from B. Rogers to D. Lloyd et al., re: Recent News & Events Magnolia Medical	KUR-MAG-DE524431	KUR-MAG-DE524432	Heindel 02 Lloyd 01 Rogers 04	402, 403, 602, 802, 805, MIL
PTX-0467		Email from M. Heindel to B. Rogers, D. Lloyd, and G. Kang, re: Clean Connect info	KUR-MAG-DE178107	KUR-MAG-DE178108	Heindel 06	402, 403, 602, 802, MIL
PTX-0468	Yes	Email from B. Rogers to M. Heindel, G. Kang, and D. Lloyd, re: diversion amount	KUR-MAG-DE481495	KUR-MAG-DE481497	Heindel 07 Rogers 07	402, 403, 602, 802, MIL
PTX-0469		Email from M. Heindel to G. Kang, re: Samples at Your House	KUR-MAG-DE481898	KUR-MAG-DE481898	Heindel 09	402, 403, 602, 802, MIL
PTX-0471	Yes	Richard G. Patton Blood Culture Contamination Definitions Can Obscure the Extent of	MAG-DEL0001064	MAG-DEL0001067		402, 403, 602, 802
PTX-0472	Yes	Document entitled, "Reduction of Blood Culture Contaminations in the Emergency	MAG-DEL0003119	MAG-DEL0003119		402, 403, 602, 802
PTX-0474	Yes	E. Skoglund, "Estimated clinical and economic impact through use of a novel blood	MAG-DEL0003133	MAG-DEL0003142		402, 403, 602, 802
PTX-0476	Yes	Jay.jpg	MAG-DEL0001068	MAG-DEL0001068		402, 403, 602, 802
PTX-0481	Yes	Magnolia Bone Marrow Biopsy - Skin Cells - Keratin Layer.pdf	MAG-DEL0001073	MAG-DEL0001105		402, 403, 602, 802
PTX-0490		U.S. Patent No. 8,647,286 entitled, "Systems and Methods for Parenterally Procuring Bodily	MAG-DEL0634750	MAG-DEL0634767		402, 403, 602, 802
PTX-0501		Correspondence from G. Bullington to K. Fitzgerald, re: Minutes of Pre-Submission Meeting	MAG-DEL0544868	MAG-DEL0544899		402, 403, 602, 802
PTX-0503		Email from K. Fitzgerald to G. Bullington, re: Q190107/A001 Meeting Minutes Accepted	MAG-DEL0826078	MAG-DEL0826078		402, 403, 602, 802
PTX-0517		K192247 Clearance Letter, Indications for Use, and 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192247.pdf	MAG-DEL0826445 MAG-DEL0546208 MAG-DEL0827239	MAG-DEL0826461 MAG-DEL0546209 MAG-DEL0827255		402, 403, 602, 802
PTX-0519		K200661 Clearance Letter available at:	MAG-DEL0827231	MAG-DEL0827238		402, 403, 602, 802
PTX-0521		Email from B. Rogers to G. Kang re: Magnolia Medical	KUR-MAG-DE504493	KUR-MAG-DE504493	Kang 05 Rogers 03	402, 403, 602, 701, 802, MIL
PTX-0522		Document entitled, "Telecon with Matt, Heindel, Dave Lloyd at Bob Rogers home will be	KUR-MAG-DE178083	KUR-MAG-DE178085	Rogers 06	402, 403, 602, 802, MIL
PTX-0523		Email from M. Heindel to G. Kang, re: WVU	KUR-MAG-DE482184	KUR-MAG-DE482184	Heindel 10	402, 403, 602, 802, MIL
PTX-0524		Email from G. Kang to M. Heindel, re: WVU	KUR-MAG-DE482185	KUR-MAG-DE482185	Rogers 09	402, 403, 602, 802, MIL
PTX-0525		Kuin.com Specifications Document	KUR-MAG-DE118243	KUR-MAG-DE118250	Rogers 23	402, 403, 602, 802, MIL
PTX-0526		Email from M. Heindel to B. Rogers and D. Lloyd, re: Magnolia	KUR-MAG-DE013908	KUR-MAG-DE013908	Heindel 12	402, 403, 602, 802, MIL
PTX-0527		Email from G. Kang to D. Lloyd et al., re: Magnolia Medical: New Funding of SteriPath for	K PROD011948	K PROD011949	Kang 15	402, 403, 602, 802, MIL
PTX-0529		Email from B. Rogers to T. Krvaric et al., re: FDA Assistance request Atts: K4 MagnoliaSteriPath Evaluation updated20170822A.pdf; memo21 -Aug-2011.	K_PROD013378	K_PROD013379	Kang 14	402, 403, 602, 802

* Magnolia provides the marking of evidence by phase herein in reliance on Kurin's May 10, 2022 email confirming that "Kurin will not argue that Magnolia's good-faith disclosures of evidence by phase are binding or preclusive."

EXHIBIT 3

FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL)	
TECHNOLOGIES, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-97-CFC (CJB)
)	
KURIN, INC.,)	
)	
Defendant.)	
_____)	

EXHIBIT 16

**MAGNOLIA’S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 6:
TO EXCLUDE EVIDENCE OR ARGUMENT
DEVIATING FROM CLAIM-TO-PRODUCT COMPARISON**

Kurin concedes that it cannot argue non-infringement “simply because the Kurin Lock is different from commercial or the specifications’ preferred embodiments.” Opp’n at 2. But the law requires more. In the infringement analysis, any comparison of the accused device to a commercial or disclosed embodiment is improper because it is irrelevant and invites confusion. Mot. at 2–3.

Kurin’s other arguments fare no better. Mere mention of a Magnolia product does not open the door for Kurin to make an improper comparison. And Magnolia’s expert will not compare the parties’ devices to show infringement.

Moreover, Kurin’s brief confirms that its expert will cross the line into improper claim construction testimony, inviting jury confusion. Opp’n at 3; *see, e.g.*, Ex. 16.1 ¶ 140. Kurin and its expert should be “precluded from testifying that specification and commercial embodiments support their views regarding the plain and ordinary meaning of claim terms.” *EMC Corp. v. Pure Storage, Inc.*, C.A. No. 13-1985-RGA, 2016 WL 775742, at *4 (D. Del. Feb. 25, 2016). Indeed, Kurin concedes it may not “present evidence or argument that any plain-and-ordinary-meaning term should be defined according to a special meaning from the intrinsic record.” Ex. 16.2 (Email from Catherine Nyarady to Philip Sheng (May 13, 2022)).

Kurin’s DOE cases are similarly inapposite. None refutes the rule that comparisons to embodiments are improper in the infringement analysis. Mot. at 1; *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985).

EXHIBIT 16.2

From: Sheng, Philip T.
Sent: Friday, May 13, 2022 7:04 PM
To: Nyarady, Catherine
Cc: Groombridge, Nicholas; Reich, Joshua D; Kelly Farnan (farnan@rlf.com); Ramani, Ashok; Smith, Rodger; dpw.service.mmt; Raman, Kripa; Barel, Ariella C; Raucci, Anthony D.; Block, Micah G.
Subject: RE: Magnolia v. Kurin - List of MILs

Hi Catherine,

We disagree with your characterizations of the call, especially your suggestion that we agreed that experts can use embodiments as examples to demonstrate their understanding of the plain and ordinary meaning of a term. That is what our MIL seeks to preclude. It does not sound like we will be able to reach an agreement on any of Magnolia's MILs, and we will proceed accordingly. With respect to Kurin's MILs, we have discussed internally and cannot agree to any of them, including Kurin's MILs seeking to preclude evidence of its future products and other litigations.

Best,
Phil

Philip T. Sheng

Davis Polk & Wardwell LLP
+1 650 752 2038 office
+1 805 405 4358 mobile
philip.sheng@davispolk.com

From: Nyarady, Catherine <cnyarady@paulweiss.com>
Sent: Friday, May 13, 2022 2:45 PM
To: Sheng, Philip T. <philip.sheng@davispolk.com>
Cc: Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; Kelly Farnan (farnan@rlf.com) <farnan@rlf.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Smith, Rodger <RSmith@morrisnichols.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>; Raman, Kripa <kraman@paulweiss.com>; Barel, Ariella C <abarel@paulweiss.com>; Raucci, Anthony D. <araucci@morrisnichols.com>; Block, Micah G. <micah.block@davispolk.com>
Subject: RE: Magnolia v. Kurin - List of MILs

Phil,

As an initial matter, my concerns on the meet and confer extended beyond the fact that the MIL as drafted would exclude the court's construction. Indeed, I specifically pointed out that the plain and ordinary meaning of a term is a question for the experts, the experts will have to testify as to what they understand any such term to mean, and that the patent can be discussed if relevant to that understanding. In response, I understood Micah to be agreeing that the experts can use embodiments as an example to demonstrate the expert's understanding, but that the expert may not use the embodiments or any other part of the specification as defining or limiting the term's meaning.

With respect to your proposal, Kurin already agreed on the meet and confer "not to present evidence or argument that any plain-and-ordinary-meaning term should be defined according to a special meaning from the intrinsic record" and agreed that neither party should argue (or re-argue) claim construction to the jury.

Kurin's position on Antonsson's paragraph 140 has not changed since the Daubert briefing and hearing. The opinion in that paragraph does not violate the above agreement and is consistent with the legal boundaries, including as articulated by Micah. We also note that this argument was denied as moot when the Court ruled to allow Antonsson to use the word "isolate." (See D.I. 297 at 13-14 (identifying the same paragraph from Dr. Antonsson's report and citing *Ferring Pharms* in support of its argument); D.I. 347 at 18-19; 2/10/2022 Hearing Transcript at 16:10-12 (denying D.I. 294 as moot).) Dr. Antonsson provides his understanding of the plain and ordinary meaning of the term "sequester" and then points to the patent's embodiments that he notes are consistent with his understanding. This is proper expert testimony. Thus, it appears the parties disagree on the application of the law here and further agreement is unlikely.

Kurin reserves all rights with respect to any other issues raised in your email, including whether any arguments were "abandoned."

During our meet and confer, your team agreed to get back to us on whether we could reach any agreement on Kurin's MILs. Specifically, we wanted confirmation that Magnolia will not be introducing evidence of Kurin products not in suit. I also mentioned not having testimony on Kurin ongoing R&D. We confirmed that we also will not introduce such evidence of Kurin products not in suit. Please let me know where Magnolia landed on this issue.

Also, I raised the issue of other litigations – both between the parties and against other parties. It is Kurin's view that such litigations are irrelevant. Magnolia indicated that it might be able to find a compromise regarding the California case between the parties. Please let us know if you have a proposal. Your team also said it would consider the issue of other litigations not between the parties, and that you might not be able to "whitewash [prior litigations] from [Bob's] record" but you agreed to consider it further. What is Magnolia's final position?

Regards,
Catherine

Catherine Nyarady | Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas | New York, NY 10019-6064
212 373 3532 (Direct Phone) | 212 492 0532 (Direct Fax)
cnyarady@paulweiss.com | www.paulweiss.com

From: Sheng, Philip T. <philip.sheng@davispolk.com>
Sent: Wednesday, May 11, 2022 6:39 PM
To: Nyarady, Catherine <cnyarady@paulweiss.com>
Cc: Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; Kelly Farnan <farnan@rlf.com> <farnan@rlf.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Smith, Rodger <RSmith@morrisnichols.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>; Raman, Kripa <kraman@paulweiss.com>; Barel, Ariella C <abarel@paulweiss.com>; Raucci, Anthony D. <araucci@morrisnichols.com>; Block, Micah G. <micah.block@davispolk.com>
Subject: RE: Magnolia v. Kurin - List of MILs

Hi Catherine,

I write to follow up regarding Magnolia's proposed MIL No. 5 seeking to "exclude presentation of claim-construction evidence or argument to the jury, including without limitation any attempt to define or limit a term's 'plain and ordinary meaning' by reference to a specific embodiment." We understand your concern from our meet-and-confer that as worded the MIL could exclude presentation of the court's claim-constructions. As we confirmed to you, that is not our intent. Rather, as we explained on the call, our intent is to seek to exclude

attempts to argue (or re-argue) claim construction to the jury, including attempts to define or limit a term's plain and ordinary meaning by reference to specific uses in the intrinsic record, such as specific embodiments.

For example, in his non-infringement expert report, Dr. Antonsson opined:

I understand the claim term "sequester" to be a synonym for the word "isolate". This understanding is **consistent with the embodiments** disclosed in the '001 Patent, all of which feature a "reservoir" that is sealed to isolate or sequester a volume of fluid. **The embodiments disclosed in the '001 Patent all physically isolate** the initial portion of blood withdrawn from the patient in the reservoir from any subsequent blood that flows to the sample collection vessel.

Antonsson Rpt. ¶ 140 (emphases added). This is an improper argument that the plain and ordinary meaning of "sequester" is defined or limited according to a particular physical isolation in disclosed embodiments. See also Antonsson Rpt. ¶ 252 (similar improper claim construction argument with respect to "initial volume" and "subsequent volume," now abandoned per Feb. 10, 2022 Hr'g Tr. at 9:22-10:16).

Any such opinion or testimony is improper. *E.g., Ferring Pharms. Inc. v. PAR Pharm., Inc.*, C.A. No. 15-173-RGA, 2016 WL 6471246, at *1 (D. Del. Oct. 28, 2016) ("Expert testimony about the plain and ordinary meaning of claim terms supported by reference to specification and prosecution history would constitute impermissible claim construction.").

Will Kurin agree not to present evidence or argument that any plain-and-ordinary-meaning term should be defined according to a special meaning from the intrinsic record, and specifically not to present "expert testimony about the plain and ordinary meaning of claim terms supported by reference to specification and prosecution history"?

Best,
Phil

Philip T. Sheng

Davis Polk & Wardwell LLP
+1 650 752 2038 office
+1 805 405 4358 mobile
philip.sheng@davispolk.com

From: Sheng, Philip T.

Sent: Wednesday, May 4, 2022 3:00 PM

To: Nyarady, Catherine <cnyarady@paulweiss.com>

Cc: Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; Kelly Farnan (farnan@rlf.com) <farnan@rlf.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Smith, Rodger <RSmith@morrisnichols.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>; Raman, Kripa <kraman@paulweiss.com>; Barel, Ariella C <abarel@paulweiss.com>; Raucci, Anthony D. <araucci@morrisnichols.com>; Block, Micah G. <micah.block@davispolk.com>

Subject: Magnolia v. Kurin - List of MILs

Hi Catherine,

Magnolia identifies the following motions *in limine* it may raise with the Court:

- i. Magnolia seeks to preclude Kurin from referencing Kurin's own patents
- ii. Magnolia seeks to exclude evidence or argument that Magnolia drafted its patent claims on Kurin statements and/or products

- iii. Magnolia seeks to exclude evidence or argument comparing the Kurin Lock to any Magnolia product or otherwise deviating from claim-to-product comparison
- iv. [REDACTED]
- v. Magnolia seeks to exclude presentation of claim-construction evidence or argument to the jury, including without limitation any attempt to define or limit a term's "plain and ordinary meaning" by reference to a specific embodiment

Best,
Phil

Philip T. Sheng

Davis Polk & Wardwell LLP
+1 650 752 2038 office
+1 805 405 4358 mobile
philip.sheng@davispolk.com

This message is intended only for the use of the Addressee and may contain information that is privileged and confidential. If you are not the intended recipient, you are hereby notified that any dissemination of this communication is strictly prohibited. If you have received this communication in error, please erase all copies of the message and its attachments and notify us immediately.

EXHIBIT 17

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL)	
TECHNOLOGIES, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-97-CFC (CJB)
)	
KURIN, INC.,)	
)	
Defendant.)	
_____)	

EXHIBIT 17

**KURIN’S MOTION *IN LIMINE* NO. 1 TO PRECLUDE
EVIDENCE OR ARGUMENT RELYING ON
DR. SANTIAGO’S NEW DEFINITION OF RESEVOIR**

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**


MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

)
)
)
) C.A. No. 1:19-cv-00097-CFC
) (CJB)
)
) 
)
)
)
)

**KURIN’S MOTION *IN LIMINE* NO. 1 TO PRECLUDE
EVIDENCE OR ARGUMENT RELYING ON
DR. SANTIAGO’S NEW DEFINITION OF RESERVOIR**

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP

1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000

Attorneys for Defendant Kurin, Inc.

May 17, 2022

TABLE OF AUTHORITIES

Page(s)

Cases

<i>ASUS Comp. Int’l v. Round Rock Rsch., LLC</i> , 2014 WL 1463609 (N.D. Cal. Apr. 11, 2014)	2
<i>Finjan, Inc. v. Rapid7, Inc.</i> , 2020 WL 5798545 (D. Del. Sept. 29, 2020)	2
<i>Intellectual Ventures I v. AT&T Mobility LLC</i> , 2017 WL 658469 (D. Del. Feb. 14, 2017)	3
<i>Pharmacyclics LLC v. Cipla Ltd.</i> , 2020 WL 6581643 (D. Del. Nov. 10, 2020)	1, 3
<i>TQ Delta, LLC v. ADTRAN, Inc.</i> , 2019 WL 4346530 (D. Del. Sept. 12, 2019)	2
<i>Trading Techs. Int’l, Inc. v. CQG, Inc.</i> , 2014 WL 4477932 (N.D. Ill. Sept. 10, 2014)	2
<i>Viatech Techs., Inc. v. Microsoft Corp.</i> , 2021 WL 663057 (D. Del. Feb. 19, 2021)	1, 2, 3

Other Authorities

Fed. R. Civ. P. 26(a)	1, 2
Fed. R. Civ. P. 37(c)(1)	1, 2

Kurin respectfully moves to preclude Magnolia from presenting at trial an untimely infringement theory on the claim term “reservoir” that was disclosed only in its technical expert’s opening expert report and deposition.¹

A patentee must timely disclose its infringement contentions during fact discovery. *See* Fed. R. Civ. P. 26(a), 37(c)(1); D.I. 24 at 1–2. Infringement theories disclosed instead for the first time in expert discovery are excluded as untimely. *Viotech Techs., Inc. v. Microsoft Corp.*, 2021 WL 663057, at *2 (D. Del. Feb. 19, 2021); *see also* *Pharmacyclics LLC v. Cipla Ltd.*, 2020 WL 6581643, at *3 (D. Del. Nov. 10, 2020); Ex. 2 at 25:2–26:2.

Each of Magnolia’s *three sets* of infringement contentions identified the *entire* U-shaped side channel of the Kurin Lock as the alleged “reservoir”. Ex. 3 at 4–5; Ex. 4 at 5–6; Ex. 5 at 5–6, 10. In response, during fact discovery, Kurin engaged a third-party to design and test whether blood in this alleged “reservoir” was “sequestered”. *See* Ex. 6 at 6–12, 14–16; Ex. 7 ¶¶ 0091–0119, App. 1. Magnolia expert Dr. Santiago performed similar tests. Both learned that the blood in the U-shaped channel is **not** “sequestered” because there is mixing. *See id.*; Ex. 8 ¶¶ 82–92. In response, Magnolia introduced an entirely new theory *after* the

¹ Because this untimely “reservoir” theory was never disclosed in Magnolia’s contentions, Kurin requested agreement that Magnolia would not present this theory at trial. *See* Ex. 1. Magnolia responded that it does intend to present this theory without amending its contentions. Kurin brings this motion to resolve this dispute outside the jury’s presence and before trial.

close of fact discovery and *only* in Dr. Santiago’s Opening Expert Report: the “reservoir” is only *the small, oval-shaped region of the inner leg of the U-shaped side channel*. Ex. 8 ¶ 136. Dr. Santiago changed the scope of the new theory even further at deposition to include additional possible “reservoirs”. See Ex. 9 at 186:3–211:9. Magnolia never moved to amend its contentions to add this theory, and cannot because it lacks good cause. D.I. 24 at 1–2, 6–7.

Magnolia failed to comply with its Rule 26 obligations. *TQ Delta, LLC v. ADTRAN, Inc.*, 2019 WL 4346530, at *2 (D. Del. Sept. 12, 2019); *Finjan, Inc. v. Rapid7, Inc.*, 2020 WL 5798545, at *3–4 (D. Del. Sept. 29, 2020); *ASUS Comp. Int’l v. Round Rock Rsch., LLC*, 2014 WL 1463609, at *1 (N.D. Cal. Apr. 11, 2014); *Trading Techs. Int’l, Inc. v. CQG, Inc.*, 2014 WL 4477932, at *1 (N.D. Ill. Sept. 10, 2014). Thus, it may not present the theory at trial “unless the failure was substantially justified or his harmless.” Fed. R. Civ. P. 37(c)(1). Here, all the factors of the governing *Pennypack* Rule 37 analysis favor exclusion. *Viatech Techs.*, 2021 WL 663057, at *1.

Prejudice to Kurin and the possibility of cure (factors 1–3): Kurin relied on Magnolia’s contentions during fact discovery to develop its testing and evidence in support of its non-infringement defense. These tests targeted and refuted Magnolia’s original “reservoir” theory and took significant time, effort and money to design and implement. See Ex. 6 at 6–12, 14–16, 34; Ex. 7 ¶¶ 0091–0119, App.

1. Kurin did not, and could not reasonably be expected to, redo such testing to target a new and different “reservoir” theory that was evolving still further as expert discovery progressed. Magnolia’s untimely post-fact discovery about face thus deprived Kurin of the ability to properly address Magnolia’s new infringement theory head on. Only exclusion can cure this late-stage prejudice. *See Viatech Techs.*, 2021 WL 663057, at *2; *see also Pharmacyclics*, 2020 WL 6581643, at *2.

Magnolia’s bad faith (factor 4):² Prior to the close of fact discovery Magnolia was aware Kurin relied on, and adduced noninfringement evidence rebutting, Magnolia’s original, disclosed, “reservoir” theory. *See* Ex. 6 at 6–12, 14–16, 34. In spite of this, and despite *serving amended infringement contentions shortly before the close of fact discovery*, Magnolia waited until expert discovery to blindsides Kurin with a new and different theory. Even as of today, Magnolia has never sought to amend its contentions.

Importance of the information to Magnolia (factor 5): Magnolia’s counsel has stated that Magnolia has “viable infringement arguments” under its original theory, (Ex. 10 at 31:7–17), making this new untimely theory, at most, an alternate, less important theory, favoring exclusion. *Viatech*, 2021 WL 663057, at *2.

Thus, the Court should preclude Magnolia’s untimely theory at trial.

² The presence of bad faith or willfulness supports but is not required for exclusion. *Intellectual Ventures I v. AT&T Mobility LLC*, 2017 WL 658469, at *5–6 (D. Del. Feb. 14, 2017).

RICHARDS, LAYTON & FINGER,
P.A.

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
kraman@paulweiss.com
jreich@paulweiss.com
abarel@paulweiss.com

/s/ Kelly E. Farnan
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

May 17, 2022

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**DECLARATION OF ARIELLA BAREL IN SUPPORT OF KURIN, INC.'S
MOTION *IN LIMINE* NO. 1 TO PRECLUDE EVIDENCE OR ARGUMENT
RELYING ON DR. SANTIAGO'S NEW DEFINITION OF RESERVOIR**

I, Ariella Barel, declare as follows:

I am a member in good standing of the bar of the State of New York, First Department and am associated with Paul, Weiss, Rifkind, Wharton & Garrison LLP, counsel for Defendant Kurin, Inc. (“Kurin”) in this action. I have been admitted *pro hac vice* for this matter. I respectfully submit this Declaration in support of Kurin’s Motion *in Limine*, which is filed herewith.

1. Attached hereto as **Exhibit 1** is a true and correct copy of the email from C. Nyarady to M. Block entitled “RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB,” dated April 13, 2022.

2. Attached hereto as **Exhibit 2** is a true and correct copy of an excerpt of the transcript of August 3, 2021 Hearing in *Koki Holdings Co. Ltd. v. Kyocera Senco Industrial Tools, Inc.*, No. 18-313-CFC-CJB.

3. Attached hereto as **Exhibit 3** is a true and correct copy of an excerpt of Attachment A to Magnolia's Infringement Contentions, dated July 17, 2019.

4. Attached hereto as **Exhibit 4** is a true and correct copy of an excerpt of the letter from C. Drakulich to K. Boyd entitled "Protective Order, Discovery and Case Management Issues (*Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, No. 19-00097-CFC (USDC-DE)), dated September 24, 2019.

5. Attached hereto as **Exhibit 5** is a true and correct copy of an excerpt of Attachment A to Magnolia's First Amended Infringement Contentions, dated July 17, 2020.

6. Attached hereto as **Exhibit 6** is a true and correct copy of an excerpt of Defendant Kurin, Inc.'s Supplemental Responses to Plaintiff Magnolia Medical Technologies, Inc.'s Interrogatories to Defendant Kurin, Inc. (Nos. 2, 11, 12, and 14), dated August 25, 2020.

7. Attached hereto as **Exhibit 7** is a true and correct copy of an excerpt of the Rebuttal Expert Report of Erik K. Antonsson, dated February 18, 2021.

8. Attached hereto as **Exhibit 8** is a true and correct copy of an excerpt of the Opening Expert Report of Dr. Juan G. Santiago Regarding Infringement of U.S. Patent Nos. 9,855,001 and 10,039,483, dated January 15, 2021.

9. Attached hereto as **Exhibit 9** is a true and correct copy of an excerpt of the transcript of the April 20, 2021 deposition of Dr. Juan G. Santiago.

10. Attached hereto as **Exhibit 10** is a true and correct copy of an excerpt of the transcript of the February 10, 2022 *Daubert* Hearing.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on May 17, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 1

Barel, Ariella C

From: Nyarady, Catherine
Sent: Wednesday, April 13, 2022 1:31 PM
To: Block, Micah G.
Cc: Smith, Rodger; Ramani, Ashok; Lisson, David; Bi, Kathryn; Sheng, Philip T.; serge.voronov@davispolk.com; Farnan, Kelly E.; Pedi, Nicole K.; Groombridge, Nicholas; Reich, Joshua D; dpw.service.mmt; Raman, Kripa; Barel, Ariella C
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Dear Micah,

On March 1, 2022 Kurin served a supplemental expert report of Dr. Antonsson, limited to a short response to Dr. Santiago's new opinions not previously disclosed in Magnolia's infringement contentions. During our March 11, 2022 meet and confer, you took the position that theories outside of a party's contentions are not properly in the case, and stated that if Kurin wanted to serve a supplemental expert report it needed to move to amend its contentions and seek permission for a supplemental expert report. Per your email below, it appears that Magnolia intends to take that position at trial. We write to advise you that, consistent with Magnolia's position taken during the meet and confer, Kurin will be moving to exclude Dr. Santiago's "reservoir" theory of infringement, which was not disclosed in Magnolia's infringement contentions and is thus not properly in the case according to Magnolia. This "reservoir" theory was untimely and disclosed for the first time in Dr. Santiago's Opening Report and substantively elaborated on at his subsequent deposition. Magnolia never moved for permission to add to the case these new infringement theories not disclosed in its contentions.

Regards,
Catherine

Catherine Nyarady | Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas | New York, NY 10019-6064
212 373 3532 (Direct Phone) | 212 492 0532 (Direct Fax)
cnyarady@paulweiss.com | www.paulweiss.com

From: Block, Micah G. <micah.block@davispolk.com>
Sent: Wednesday, March 23, 2022 1:09 PM
To: Nyarady, Catherine <cnyarady@paulweiss.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; serge.voronov@davispolk.com; Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Dear Catherine,

Following up on our recent discussions, as you know we believe the Antonsson supplement is untimely and improper, particularly given that it was served in violation of the Court's schedule and without leave of the Court. If Kurin wished to expand Dr. Antonsson's disclosures, it should have sought leave to do so.

Magnolia reserves all rights and objections with respect to the supplement and the issues and opinions it purports to raise, including without limitation waiver arguments and objections to admissibility.

Best,
Micah

From: Nyarady, Catherine <cnyarady@paulweiss.com>
Sent: Friday, March 18, 2022 1:01 PM
To: Block, Micah G. <micah.block@davispolk.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; Voronov, Serge A. <serge.voronov@davispolk.com>; Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

That works. Thanks, and have a good weekend!

Catherine Nyarady | Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas | New York, NY 10019-6064
212 373 3532 (Direct Phone) | 212 492 0532 (Direct Fax)
cnyarady@paulweiss.com | www.paulweiss.com

From: Block, Micah G. <micah.block@davispolk.com>
Date: Friday, Mar 18, 2022, 3:59 PM
To: Nyarady, Catherine <cnyarady@paulweiss.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; serge.voronov@davispolk.com <serge.voronov@davispolk.com>; Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Thanks Catherine. 8:30am PT on Monday works for me. I'll call you then at your direct number below (unless you prefer something different, in which case just let me know). Have a good weekend.

Best,
Micah

From: Nyarady, Catherine <cnyarady@paulweiss.com>
Sent: Friday, March 18, 2022 12:57 PM
To: Block, Micah G. <micah.block@davispolk.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; Voronov, Serge A. <serge.voronov@davispolk.com>; Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Hi Micah,

Apologies but I am tied up the rest of the day. I am free 8:30-9:30 PT if you want to talk first thing Monday. If that time doesn't work just let me know when is good for you.

Thanks,
Catherine

Catherine Nyarady | Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas | New York, NY 10019-6064
212 373 3532 (Direct Phone) | 212 492 0532 (Direct Fax)
cnyarady@paulweiss.com | www.paulweiss.com

From: Block, Micah G. <micah.block@davispolk.com>
Date: Friday, Mar 18, 2022, 3:14 PM
To: Nyarady, Catherine <cnyarady@paulweiss.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>, Ramani, Ashok <ashok.ramani@davispolk.com>, Lisson, David <david.lisson@davispolk.com>, Bi, Kathryn <kathryn.bi@davispolk.com>, Sheng, Philip T. <philip.sheng@davispolk.com>, serge.voronov@davispolk.com <serge.voronov@davispolk.com>, Farnan, Kelly E. <Farnan@RLF.com>, Pedi, Nicole K. <Pedi@rlf.com>, Groombridge, Nicholas <ngroombridge@paulweiss.com>, Reich, Joshua D <jreich@paulweiss.com>, dpw.service.mmt <dpw.service.mmt@davispolk.com>
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Hi Catherine –

With apologies for the Friday afternoon email, do you have time for a short call today? I'm quite flexible this afternoon. I wanted to follow up on a couple of our recent discussions. We can look to Monday or later next week if that's better for you.

Thanks,
Micah

From: Nyarady, Catherine <cnyarady@paulweiss.com>
Sent: Wednesday, March 9, 2022 11:01 AM
To: Block, Micah G. <micah.block@davispolk.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; Voronov, Serge A. <serge.voronov@davispolk.com>; Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>
Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

We can do Friday at 4:00 ET.

Catherine Nyarady | Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas | New York, NY 10019-6064
212 373 3532 (Direct Phone) | 212 492 0532 (Direct Fax)
cnyarady@paulweiss.com | www.paulweiss.com

From: Block, Micah G. <micah.block@davispolk.com>
Sent: Wednesday, March 9, 2022 1:41 PM
To: Nyarady, Catherine <cnyarady@paulweiss.com>
Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T.

<philip.sheng@davispolk.com>; serge.voronov@davispolk.com; Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>; dpw.service.mmt <dpw.service.mmt@davispolk.com>

Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Thanks Catherine. Do you have time to confer this Friday at 11am or after 4pm ET?

Also please note the service email address for the Davis Polk team, copied here – dpw.service.mmt@davispolk.com. We'd appreciate it if you could include that address generally for case correspondence going forward.

Best,
Micah

Micah G. Block

Davis Polk & Wardwell LLP
+1 650 752 2023 office
+1 650 353 6257 mobile
micah.block@davispolk.com

From: Nyarady, Catherine <cnyarady@paulweiss.com>

Sent: Monday, March 7, 2022 2:58 PM

To: Block, Micah G. <micah.block@davispolk.com>

Cc: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T.

<philip.sheng@davispolk.com>; Voronov, Serge A. <serge.voronov@davispolk.com>; Farnan, Kelly E.

<Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>

Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Dear Micah,

Magnolia has been on notice of Dr. Antonsson's opinions on indefiniteness since his rebuttal report was served on February 18, 2021 and the bases of those opinions available to him at the time of that report. Specifically, Magnolia has been aware that it was Dr. Antonsson's opinion that Dr. Santiago's new, previously undisclosed position in his opening expert report as to what constituted the "reservoir" in Kurin's device rendered the claims indefinite. Magnolia has also been aware since at least May 27, 2021 of Kurin's position that Dr. Santiago should be precluded from testifying as to his new, previously undisclosed position, which materially departed from Magnolia's infringement contentions. (D.I. 288.) In view of the Court's February 10, 2022 ruling denying Kurin's Daubert motion seeking to preclude Dr. Santiago's testimony, Dr. Antonsson's Supplemental Report was served to address additional bases for his opinions that were unavailable to him at the time of his rebuttal report. Kurin and Dr. Antonsson made every effort to serve promptly Dr. Antonsson's Supplemental Report, doing so the day after the February 10 Hearing Transcript was obtained. We are happy to meet and confer, if needed, at your convenience.

Regards,
Catherine

Catherine Nyarady | Partner
Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas | New York, NY 10019-6064
212 373 3532 (Direct Phone) | 212 492 0532 (Direct Fax)
cnyarady@paulweiss.com | www.paulweiss.com

From: Block, Micah G. <micah.block@davispolk.com>

Sent: Friday, March 4, 2022 8:13 PM

To: Farnan, Kelly E. <Farnan@RLF.com>; Pedi, Nicole K. <Pedi@rlf.com>; Groombridge, Nicholas <ngroombridge@paulweiss.com>; Nyarady, Catherine <cnyarady@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>

Cc: dpw.service.mmt <dpw.service.mmt@davispolk.com>; Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; serge.voronov@davispolk.com

Subject: RE: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Dear Counsel –

We have received the expert report that was attached to the email below. We're not aware of any prior notice, nor any request for leave to submit this report, which as you know comes long after the Court's deadlines for expert disclosures, close of discovery, Daubert motions, etc. To the extent Kurin contends that this document is timely, or that there is justification for its untimeliness, would you please explain the basis for that contention?

Plaintiff reserves all rights and will consider next steps in light of Kurin's position.

Thanks,

Micah

Micah G. Block

Davis Polk & Wardwell LLP

+1 650 752 2023 office

+1 650 353 6257 mobile

micah.block@davispolk.com

From: Farnan, Kelly E. <Farnan@RLF.com>

Sent: Tuesday, March 1, 2022 1:30 PM

To: Smith, Rodger <RSmith@morrisnichols.com>; Ramani, Ashok <ashok.ramani@davispolk.com>; Lisson, David <david.lisson@davispolk.com>; Bi, Kathryn <kathryn.bi@davispolk.com>; Block, Micah G. <micah.block@davispolk.com>; Sheng, Philip T. <philip.sheng@davispolk.com>; Voronov, Serge A. <serge.voronov@davispolk.com>

Cc: Pedi, Nicole K. <Pedi@rlf.com>; ngroombridge@paulweiss.com; Nyarady, Catherine <cnyarady@paulweiss.com>; Reich, Joshua D <jreich@paulweiss.com>

Subject: Magnolia Medical v. Kurin, C.A. No. 19-097-CFC-CJB

Attached please find a service copy of the Supplement to Opening Expert Report of Erik K. Antonsson and the corresponding Notice of Service.

Kelly E. Farnan

Richards, Layton & Finger, P.A.

920 North King St.

Wilmington, DE 19801

Direct Dial: (302) 651-7705

E-Mail: farnan@rlf.com

The information contained in this electronic communication is intended only for the use of the individual or entity named above and may be privileged and/or confidential. If the reader of this message is not the intended recipient, you are hereby notified that any unauthorized dissemination, distribution or copying of

this communication is strictly prohibited by law. If you have received this communication in error, please immediately notify us by return e-mail or telephone (302-651-7700) and destroy the original message. Thank you.

This message is intended only for the use of the Addressee and may contain information that is privileged and confidential. If you are not the intended recipient, you are hereby notified that any dissemination of this communication is strictly prohibited. If you have received this communication in error, please erase all copies of the message and its attachments and notify us immediately.

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

KOKI HOLDINGS CO. LTD., : CIVIL ACTION
Plaintiff, :
vs. :
KYOCERA Senco INDUSTRIAL :
TOOLS, INC., :
Defendant. : NO. 18-313-CFC-CJB

- - -

Wilmington, Delaware
Tuesday, August 3, 2021
2:50 o'clock, p.m.

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, Chief Judge

- - -

APPEARANCES:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
BY: KAREN JACOBS, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

1 APPEARANCES (Continued) :

2
3 McDERMOTT WILL & EMERY LLP
4 BY: AMOL A. PARIKH, ESQ. and
(Chicago, Illinois)

5 -and-

6
7 McDERMOTT WILL & EMERY LLP
8 BY: PAUL DEVINSKY, ESQ.
(Washington, D.C.)

9 Counsel for Plaintiff

10
11 RICHARDS, LAYTON & FINGER, P.A.
12 BY: KELLY E. FARNAN, ESQ.

13 -and-

14
15 VEDDER PRICE P.C.
16 BY: ROBERT S. RIGG, ESQ.,
17 DANIEL SHULMAN, ESQ. and
JOHN K. BURKE, ESQ.
(Chicago, Illinois)

18 Counsel for Defendant

19 - - -
20
21
22
23
24
25

1 MR. RIGG: Thank you, Your Honor.

2 THE COURT: All right. How do you want to
3 proceed? Do you want to do the motions in limine or do you
4 have issues you want to raise first.

5 MR. PARIKH: We're fine with proceeding with the
6 motions in limine.

7 THE COURT: Okay. All right. Let's start.

8 Okay. So the first is the defendant's motion,
9 right, to exclude -- wait. Sorry. The first is the
10 plaintiff's motion to exclude the untimely or allegedly
11 untimely invalidity defenses. All right.

12 Actually, before you get started, because I will
13 forget this. You got the jury checklist from my deputy
14 clerk?

15 MR. PARIKH: Yes.

16 MS. JACOBS: Yes.

17 THE COURT: Any questions about that?

18 MS. FARNAN: No.

19 THE COURT: This screen here. If you need to
20 replace it, just call chambers and make arrangements for
21 that. We're in trial the week before you all are, so you
22 might want to call up next week and get that arranged and
23 maybe come in. If you want to test it, do it next week
24 would be my suggestion.

25 All right. Sorry. Just one more issue. Okay.

1 Go ahead.

2 MR. PARIKH: Okay. Your Honor, the first motion
3 in limine or plaintiff's motion in limine one relates to an
4 untimely obviousness theory that Kyocera is putting forth.

5 There's no dispute that the obviousness theory
6 is untimely. It was not provided during discovery. The
7 first time it was provided was in the pretrial order.
8 Understanding that the test for whether this new theory
9 should come in or whether the failure to disclose it earlier
10 was justified or it's not harmless, neither of those factors
11 are probative for the reasons that we outlined in our
12 motion.

13 First it was -- you know, the obviousness theory
14 was known, throughout all the discovery of the product it
15 was known, and it's the only theory of invalidity relating
16 to the SN325-Plus were that it was anticipated, or
17 anticipated the asserted claim and that it was -- the
18 obviousness theory was an Ishizawa reference, a patent
19 reference, that would have been modified based on the
20 SN325-Plus, which is a prior art product.

21 But there was never a theory that you would
22 actually take that prior art product and modify that prior
23 art product, and because that theory was not disclosed,
24 there was certain evidence that we didn't go into or look
25 into to see whether one of skill in the art would have

1 actually modified that prior art that way Kyocera is now
2 alleging, whether it would have been feasible and whether
3 they would have been motivated to make those changes.

4 THE COURT: Okay. Anything else?

5 MR. PARIKH: I'm happy to run through those if
6 you would like or answer any questions that the Court may
7 have.

8 THE COURT: Well, I will listen to the other
9 side.

10 MR. SHULMAN: Thank you, Your Honor. So the
11 genesis of this was it argued that the SN325-Plus was
12 anticipated because those four holes could be read --

13 THE COURT: Wait. It was anticipated or it
14 anticipated?

15 MR. PARIKH: It anticipated, sorry, the claims
16 because those four holes could be combined to be read as the
17 first channel. On summary judgment, Your Honor said no,
18 it's one channel only, and so now what we essentially argue,
19 or what we are arguing is that all along we said those four
20 channels are no different than the one channel. That was
21 the basis for the anticipation argument.

22 So if the Court is going to look at
23 justification for not raising it earlier, all of the
24 elements, all of the factors, all the facts were already
25 there. It was only after that new claim construction or the

1 claim construction that came forth from the Court after the
2 supplemented further claim construction where we said, no,
3 we're only looking at that one channel. You are not going
4 to look at all four.

5 When that happened, opposing counsel said are
6 you going to withdraw the SN325? We said no, we think we
7 can still make an obviousness argument.

8 We admit we did not amend the contentions at
9 that point. We just said, no, we think we could still make
10 an obviousness argument because all of the testimony was
11 still there.

12 On the prejudice point, I do want to point out
13 that counsel did ask our expert, Mr. Miller, at his
14 deposition specifically about the things he said he didn't
15 get a chance to ask. So this was on page 116 of
16 Mr. Miller's deposition and talking about the channel.

17 THE COURT: Hold on, please.

18 MR. PARIKH: Yes. And I don't know if this is
19 in the record, Your Honor.

20 THE COURT: I didn't see that.

21 MR. PARIKH: No. This is in response to now the
22 argument that they didn't get a chance to -- that they
23 raised in their reply, that they didn't get a chance to
24 question the witness about it. On page 116, line 5 of
25 Mr. Miller's deposition, there's a question:

1 "Is there a limit on the number of channels that
2 can be used to determine the cross-sectional area of a first
3 channel?

4 "Answer: Is there a limit? No. In this patent
5 are not putting a limit on it, no.

6 "Question. Let's say hypothetically that a
7 prior art patent had ten cross over holes with smaller
8 diameters. Would you be able to combine in your opinion the
9 cross-sectional area of all of those cross over holes to
10 obtain the cross-section of a first channel?

11 "Answer: Yes.

12 "Question: If there were 100 crossover holes,
13 you could combine the cross-sectional area of 100 of those
14 cross over holes? If there are holes, I would agree that
15 you could combine them, yes. If there were a thousand
16 crossover holes?

17 "Answer: I don't think that's practical."

18 Later in the deposition on page 136:

19 "Question: It says line 12, but don't you agree
20 that a person of ordinary skill would analyze flow
21 characteristics in determining whether to modify the SN325
22 plus to have a single hole instead of four holes?

23 "Answer: I mean, it's obvious that the
24 designers didn't want a single hole. They wanted four
25 holes, so they obviously would do that. Any designer which

1 found out how much flow area is needed for the design and
2 the 325 designers calculated they needed four."

3 Followup question: "And a person of ordinary
4 skill would also analyze flow characteristics in determining
5 whether to modify the cross-sectional area of the main valve
6 control area. Right?

7 "Answer: By adding or removing a whole to the
8 cross-sectional area, the further area. Further questions
9 about enlarging the holes were made."

10 So they clearly understood this idea that the
11 four holes versus one hole was always an issue. They asked
12 about motivation to go from four holes to one hole. All of
13 the facts that the experts are going to testify to on
14 obviousness are already in the record and so we don't think
15 that there's any prejudice, and as far as justification,
16 again, it was because the theory changed when the Court
17 decided this additional claim construction limitation that
18 we had to go from then, was essentially the same argument
19 under anticipation to obviousness, Your Honor.

20 THE COURT: Okay. Do you want to come forward?

21 MR. PARIKH: Yes.

22 THE COURT: I am having a hard time with how
23 you're really prejudiced.

24 MR. PARIKH: So maybe I can take a step back.
25 The argument before, there was an Ishizawa reference that

1 had one channel and a fairly long channel, and Kyocera's
2 argument was he would -- and it doesn't define the
3 cross-sectional area, and they have the SN325 product that
4 has four channels. You take the combined ratio of the four
5 channels in this prior art product, which are very short,
6 and you modify the Ishizawa reference to have that ratio.

7 That's the -- that was their argument before.
8 And all the questions Mr. Shulman was discussing, it was in
9 the context or in the abstract of going from four channels
10 to ten channels to a hundred channels. It wasn't looking at
11 a specific piece of prior art and saying what would happen
12 if I took those four channels in the SN325-Plus and I
13 combined that into one channel? Instead it was what if I
14 took that ratio from that prior art reference and I modify
15 it to this other reference over here? That's the analysis
16 of our expert. It was you wouldn't modify Ishizawa with
17 this ratio because it wouldn't work or it's not feasible to
18 make that modification.

19 So the prejudice, now what they are saying is
20 get rid of this reference over here and you take the SN325
21 plus and it has four holes and you're combining that into
22 one hole. The analysis that was never done and the heart of
23 the obviousness inquiry, is, one, is it feasible to take
24 those four holes and change them into one hole and what is
25 the impact on the tool?

1 These are power tools where if you make a change
2 in one area, it's going to affect the operation of the tool
3 in another area. So the question Mr. Shulman was asking or
4 that he said I asked about airflow, if you change from four
5 holes to one hole, that affects the airflow of the tool.

6 Now, one, how does that airflow change? We have
7 not been able to explore. Because you're now increasing the
8 size of a hole, that may increase the size of a tool and
9 these are tools that are compact and if you need to increase
10 the size of a tool, that may be a reason that one of
11 ordinary skill in the art would not make that change.

12 THE COURT: But does he have any -- in his
13 report, he doesn't -- he doesn't have those calculations.

14 MR. PARIKH: Our expert, Dr. Valley?

15 THE COURT: Well, yours doesn't. I know that.

16 MR. PARIKH: He does not, correct.

17 THE COURT: But does he have those calculations
18 in a report?

19 MR. PARIKH: No, they don't have the -- they did
20 not explain why one of skill in the art, or what impact
21 changing the four holes into one hole would have on a tool.
22 Their position is, these are four holes. You just change it
23 into one. But our position is that's not how these tools
24 operate. It's not just a design choice. Maybe it is a
25 design choice, but there are other impacts or effects on the

1 tool that we should have been able to explain.

2 THE COURT: Right. You're going to show that he
3 didn't do any of those. He gave no due consideration to
4 those facts. Right?

5 MR. PARIKH: That is -- yes.

6 THE COURT: In other words, he has got -- you
7 say did not disclose the theory until the pretrial order.
8 Okay. Where in the pretrial order is it? I'm looking at
9 your motion.

10 MR. PARIKH: It's in Exhibit 3 and, again, this
11 is -- this was a discussion that we had with Kyocera and
12 they agree they just say --

13 THE COURT: Hold on. Hold on, please.

14 MR. PARIKH: Yes.

15 THE COURT: I mean, I'm just curious, and I just
16 say this because just going forward. Looking at your
17 motion, I think the only description you have of what you
18 are trying to preclude from coming into evidence is just
19 your summary of what he said. Right? And I just want to
20 make sure.

21 And I don't know what he said is what I'm
22 getting at, so that's what we're walking through now. You
23 are saying in the pretrial order, so then we're on Exhibit
24 3.

25 MR. PARIKH: Two places. Exhibit 3, which is

1 defendant's statement of facts where they --

2 THE COURT: Yes.

3 MR. PARIKH: And Exhibit 5.

4 THE COURT: Let's go through them individually.

5 Okay.

6 MR. PARIKH: Okay.

7 THE COURT: So where in Exhibit 3?

8 MR. PARIKH: Well, Exhibit 3 I'm setting up. So
9 on page 2.

10 THE COURT: Okay. Where?

11 MR. PARIKH: So Section 1A-1 and 2.

12 THE COURT: All right. Well, hold on. 1A-1.
13 1A-1 just reads those are the contents of the prior art.

14 MR. PARIKH: Correct, yes.

15 THE COURT: Okay. And then where else is it?

16 MR. PARIKH: And then in Exhibit 5 on page 2.

17 THE COURT: Are you looking at the same thing?
18 I'm looking at Exhibit 3, which is defendant's statement of
19 facts. All it says on page 2 under 1A -- where are you
20 looking? 1A-1?

21 MR. PARIKH: Maybe I could direct you. It's
22 more specific in Exhibit 5, Your Honor, which is the
23 statement of law.

24 THE COURT: Okay. All right. So where are we
25 in 5?

1 MR. PARIKH: So on page 2 of Exhibit 5.

2 THE COURT: Okay.

3 MR. PARIKH: There's Roman Numeral I and then
4 invalidity, subpart A and then subpart 1.

5 THE COURT: Okay.

6 MR. PARIKH: And the issue -- the keyword is the
7 or and --

8 THE COURT: Got you. Okay.

9 MR. PARIKH: So --

10 THE COURT: So they've injected the or.

11 MR. PARIKH: That's correct.

12 THE COURT: All right. Now, this is all they've
13 said. How do you even know what they are going to say?

14 MR. PARIKH: Well, it's based on their expert
15 report and in their -- their expert is limited under the
16 Federal Rules. He has to disclose his opinions and in his
17 expert report, the opinions were --

18 THE COURT: Wait. Time out. I want to go back
19 to, you say in your motion that this defense was first
20 disclosed in the pretrial order to you. Right?

21 MR. PARIKH: Correct.

22 THE COURT: All right. And now I'm walking
23 through the pretrial order and you're showing me where it
24 was disclosed. All right.

25 So and you had no knowledge, you're saying, of

1 this defense prior to the issuance of the pretrial order.

2 Right? So you were given the pretrial order.

3 MR. PARIKH: Correct.

4 THE COURT: Okay. So how do you know what
5 they're going to say?

6 MR. PARIKH: Because we asked them about it
7 during the meet and confer. Mr. Shulman just says that they
8 are. We saw the or and we wanted to know what were their
9 invalidity arguments going to be.

10 THE COURT: Right. And you never heard about
11 that until the meet and confer, which occurred after the
12 filing of the pretrial report. You didn't have any detail
13 on how they are going to show that claim 1 of the '021
14 patent is invalid for obviousness based on and only on the
15 SN325. Right? That was the first you ever heard of it?

16 MR. PARIKH: That's correct.

17 THE COURT: Okay.

18 MR. PARIKH: And just so we're clear, I don't
19 mean to correct Your Honor, but it was during the exchange
20 of the exhibits to the pretrial order and the meet and
21 confer occurred a few days after the exchange of these
22 documents.

23 THE COURT: Okay.

24 MR. PARIKH: And at that point we raised the
25 issue and we were informed by Kyocera that they did intend

1 to argue at trial that the claims of the '012 and the '647
2 patent are invalid as obviousness based on the SN3245-Plus
3 alone and that's the proffer of the motion in limine.

4 THE COURT: Now, you said it's in their expert
5 report I think is what you said?

6 MR. PARIKH: The opinions in the expert report,
7 and I apologize, Your Honor. I have hard copies. That was
8 another exhibit which was not included by mistake in our
9 pretrial order, but I can just provide the Court with
10 copies.

11 In the expert report, Kyocera's expert alleged
12 that the claims were anticipated by the SN3245-Plus and then
13 obvious based on Ishizawa.

14 THE COURT: Combined?

15 MR. PARIKH: Combined with --

16 THE COURT: I get that, right. But you've
17 never seen an expert report where their expert explains how
18 claim 1 would be invalid for obviousness based solely on the
19 SN325.

20 MR. PARIKH: We have not.

21 THE COURT: So the only thing you know that
22 describes their theory is what you learned through meet and
23 confers or a meet and confer that occurred after you were
24 provided a draft of the pretrial order?

25 MR. PARIKH: That's correct.

1 THE COURT: Okay. And when was that?

2 MR. PARIKH: It would have been I believe
3 July -- the first week of July.

4 THE COURT: July -- in other words, less than a
5 full month ago?

6 MR. PARIKH: That's correct.

7 THE COURT: Okay. And when did I issue my
8 Markman opinion where I -- and incidentally, I didn't change
9 the construction of the claim issue. Right? I just decided
10 to construe it?

11 MR. PARIKH: We thought the construction was
12 clear on its face.

13 THE COURT: Right.

14 MR. PARIKH: It was a request for supplemental
15 construction, but the parties have --

16 THE COURT: And who made the request?

17 MR. PARIKH: Koki made the request.

18 THE COURT: Okay.

19 MR. PARIKH: Because we thought Kyocera was
20 construing the term in a way that based on prior art that
21 had come into the case late.

22 THE COURT: All right. And then I granted that
23 request and I construed it. Do you know the date I
24 construed it?

25 MS. JACOBS: March 26th, Your Honor.

1 THE COURT: Of this year?

2 MS. JACOBS: Of this year.

3 THE COURT: All right. So I construed it on
4 March 26th. And then the next you heard was sometime in
5 July. Right?

6 MR. PARIKH: That's correct, Your Honor.

7 THE COURT: More than three months later?

8 MR. PARIKH: That's correct, Your Honor.

9 THE COURT: Okay.

10 MR. PARIKH: And I would also point out that we
11 had disclosed our proposed construction, or the parties had
12 exchanged proposed constructions in February or March of 202
13 it was.

14 THE COURT: Okay. All right. Thank you. All
15 right. Anything else the defense wants to say?

16 MR. SHULMAN: Yes, Your Honor. Maybe my friend
17 had forgotten. After Your Honor issued the summary judgment
18 in March, in April and May there was a dialogue about
19 whether or not you're withdrawing 325 and we notified
20 counsel via e-mail back in May that, no, we think all of the
21 obligations for obviousness are still, still in all of the
22 expert reports and still in the case, and so they would have
23 known at least a month-and-a-half before we started
24 exchanging the pretrial order that --

25 THE COURT: Are any of these in the motions in

1 limine?

2 MR. SHULMAN: They're not because we didn't know
3 that they were going to raise them. They didn't know about
4 it frankly, Your Honor. What I just heard today is the
5 first that they didn't know about it.

6 I do want to point out though, Your Honor, one
7 other thing, and because this is -- this is the
8 inconsistency in their argument, is that they want to
9 preclude it, but they understand that everything is already
10 in the expert report and the experts can't go beyond the
11 expert report, which suggests that there's no prejudice.

12 THE COURT: Well, wait. Are you telling me that
13 they're -- just show it to me then. Is it somewhere
14 disclosed in the expert report that they solely on the
15 SN325-Plus that an artisan of skill would have made
16 modifications to make the accused product?

17 MR. SHULMAN: So we cited a number of
18 paragraphs.

19 THE COURT: Okay. Hold on. Hold on.

20 MR. SHULMAN: In our motion in limine we cited a
21 number of paragraphs both in our report, their expert's
22 response and our expert's response.

23 THE COURT: Can you slow down for a second?

24 MR. SHULMAN: Yes. Sorry, Your Honor. It's
25 page 2 of our response to their motion in limine. And I

1 would want to point out to Your Honor --

2 THE COURT: Okay.

3 MR. SHULMAN: Mr. Parikh made a comment --

4 THE COURT: Can you wait a minute so I can
5 think?

6 MR. SHULMAN: Yes.

7 THE COURT: You know, my question was where is
8 it? You might have said it, but where is the exhibit?
9 Exhibit 2, rebuttal report of Glenn Valley. Where is it?

10 MR. SHULMAN: I have it with me. I can hand it
11 up, Your Honor.

12 THE COURT: I have the pretrial order. I don't
13 have it. I tried to prepare to come in here. I don't have
14 it.

15 MR. SHULMAN: I apologize, Your Honor. There
16 must have been a miscommunication between the parties
17 filing, filing the exhibits to the motions in limine, so I
18 apologize for that.

19 I'm happy to hand it up. We will submit it
20 afterwards. I can point though you directly to Mr. Parikh's
21 comments about, well, there was no discussion of airflow,
22 because that was his primary argument about why four is not
23 one.

24 In paragraph 193 of Mr. Miller's reply report,
25 which we cited to, he specifically says, I disagree with Dr.

1 Valley's opinion that the airflow from the main valve
2 chamber in the SN325 is far more complex than of Ishizawa as
3 the flow path in 325-Plus is shorter and simpler.
4 Nevertheless, this opinion, Dr. Valley's opinion that the
5 Ishizawa design has an elongated first channel and much more
6 compact trigger valve, which undoubtedly results in
7 different flow characteristics, are irrelevant.

8 Again, he cites to the fact that none of the
9 claims talk about flow characteristics, so they were on
10 notice that our expert considered those flow
11 characteristics.

12 THE COURT: The question is were they on notice
13 you were going to argue obviousness based solely on that
14 reference. Is that disclosed in your report anywhere?

15 MR. SHULMAN: The fact -- no, we did not
16 disclose prior to letting him know the e-mail in May that we
17 were going to use the SN325 as obviousness.

18 Our position, Your Honor, is that all of the
19 facts that we will use to support obviousness are already in
20 the record.

21 THE COURT: I got that.

22 MR. SHULMAN: Okay.

23 THE COURT: I got that. But, you know,
24 disclosing the facts and disclosing the theory are two
25 different things. You didn't seek to amend your contention

1 interrogatories?

2 MR. SHULMAN: We did not, Your Honor. After we
3 put them on notice in May, we did not then additional seek
4 to amend. Right or wrong, we thought we had put them on
5 notice.

6 THE COURT: Well, you were wrong. I'm going to
7 grant the motion. I can't run trials like this and try to
8 go through, you know, what the facts are, the other expert
9 reports that isn't even attached to the pleading that I'm
10 supposed to review.

11 What I am convinced about is there was ample
12 time to seek Court intervention if you couldn't get an
13 agreement to formally move as our rules require for an
14 amendment and I'm not even sure good cause exists. I don't
15 have enough material before me to make that decision and so
16 I just think on the eve of trial, you can't do it. You have
17 not persuaded me, since I don't even have the report and
18 it's way too complicated on the issue of prejudice, but I do
19 think regardless, I mean, you guys inundated me with
20 motions.

21 So I'm going to find that it's a credible
22 allegation of prejudice and that there is a clear failure to
23 seek an amendment as required, and therefore I'm not going
24 to at this late date -- and by the way, it's also undisputed
25 that the experts never said they disclosed in the report

1 that there was an obviousness theory based solely on the
2 325N. All right. So that motion is granted.

3 Let's go to defendant's motion in limine number
4 one to exclude the testimony of commercial success.

5 MR. SHULMAN: So, Your Honor, this is a narrow
6 issue. In order to prove that there was commercial success
7 of facts related to nonobviousness, there must be a nexus
8 that exists that is more than as the Court has said, at
9 least one Court has said, do more than just say the product
10 incorporates the claimed invention, the product is
11 successful. Therefore, the invention must have caused the
12 commercial success, which is all that Dr. Valley does, and
13 they have not pointed to any other evidence besides Dr.
14 Valley's very, very general claims of commercial success for
15 which he is not being admitted as an expert.

16 The --

17 THE COURT: What do you mean by he's not being
18 admitted as an expert?

19 MR. SHULMAN: He's a technical expert, Your
20 Honor.

21 THE COURT: Well, if your beef is with his
22 qualifications, it seems to me that should have been a
23 Daubert motion. You had a deadline that has kind of come
24 and gone.

25 Now, so were the opinions disclosed?

EXHIBIT 3

Attachment A - Infringement of U.S. Patent No. 9,855,001

This chart applies the claims of Magnolia's U.S. Patent No. 9,855,001 ("the '001 patent") against Kurin's blood culture collection sets numbered K-11221, K11223, K-11225, D-11221, D-11223, D-21223, M-11221, M-11223, M-21223, T-11221, T-21221, T-11223, T-21223, D-PIV12, M-PIV12, M-PIV18, S-PIV4, and S-PIV10, (collectively, "the Accused Products").

The Accused Products are substantially similar to one another. For example, each of the Accused Products includes a Kurin Lock apparatus. *See, e.g.*, MAG-DEL0000688–693 (<https://www.kurin.com/skin-contaminant-diversion/>) at 688 ("The Kurin Lock® - Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful specimen diversion device that automates diversion during the routine process of drawing a blood culture."). Based on the information presently available to Magnolia, the Kurin Lock apparatus in Accused Products D-11221, D-21223, D-11221, D-21223, M-11221, M-11223, M-21223, T-11221, T-21221, T-11223, T-21223, D-PIV12, D-PIV18, M-PIV12, M-PIV18, S-PIV4, and S-PIV10 is identical and is described and illustrated in, for example, Kurin Drawing Numbers KUR-2005 (Top Housing) [KUR-MAG-DE001623-24], KUR-2006 (Bottom Housing) [KUR-MAG-DE001625-26], KUR-2007 (Cap) [KUR-MAG-DE001627], KUR-6010 (Hydrophobic Self-Sealing Plug) [KUR-MAG-DE001655], KUR-6011 (Umbrella Valve) [KUR-MAG-DE001656], and KUR-8036 (Assembly) [KUR-MAG-DE001659], MiniValve Part Number UM 053.002 SD (Umbrella Valve and seating suggestion) [KUR-MAG-DE003703]; Manufacturing Procedure MP-016 [KUR-MAG-DE00104-124] and the duplicates of these drawings produced throughout KUR-MAG-DE000138-2362. On information and belief, based on the limited information Kurin has provided to date and representations made by counsel for Kurin, Accused Products K-11221, K11223, K-11225 are substantially similar to the other Accused Products.

As such, Magnolia contends that, for purposes of the infringement analysis, the Accused Products are identical except where otherwise indicated below. Magnolia reserves its right to amend these contentions as additional information becomes available and in view of claim construction.

Claim 1	Accused Products
1. An apparatus for obtaining a bodily fluid sample from a patient with reduced contamination, the apparatus comprising:	<p>To the extent the preamble of claim 1 is a limitation, each of the Accused Products is an apparatus for obtaining a bodily fluid sample from a patient with reduced contamination. <i>See, e.g.</i>,</p> <p>MAG-DEL0000684–687 (https://www.kurin.com/kurin-lock-specimen-diversion-device/) at 684 ("Each Kurin® blood culture collection set features</p>

industry-leading butterfly needles and is compatible with all major blood culture bottles. The Kurin blood culture set is enhanced by a Kurin Lock® specimen diversion device enabling clinicians to automatically divert the initial aliquot of blood, which many contain skin microbes, from every draw.”)

MAG-DEL0000688–693 (<https://www.kurin.com/skin-contaminant-diversion/>) at 688 (“The Kurin Lock® - Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful specimen diversion device that automates diversion during the routine process of drawing a blood culture.”)

MAG-DEL0000680–681 (Kurin Brochure) at 680:



Blood Culture Collection Sets

Traditional blood culture collection methods provide skin microbes a direct line to the culture.

Kurin technology diverts the initial aliquot of blood which may contain skin contaminants. Roughly 20% of the microbes present in skin reside deep in the dermis.¹ With venipuncture, contaminants may be dislodged and drawn into blood culture samples leading to high rates of seemingly unavoidable false positives. Standing guard between the venipuncture site and the culture bottle, the Kurin Lock® specimen diversion device corrals blood from the venipuncture site while the clinically relevant blood sample flows into the blood culture bottle.

Id. (“Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful device that automatically diverts the initial aliquot of blood during the routine process of drawing a blood culture....Any contaminants residing in the initial ~0.15ml volume of blood (35x a standard 21G needle) are captured in the u-shaped Kurin Lock®. When the collection bottle is attached, blood flows directly from the vein into the culture bottle through a separate channel.”)

Id.:

How does it work?

Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful device that automatically diverts the initial aliquot of blood during the routine process of drawing a blood culture.



Serves as a flash chamber to provide visual confirmation of proper needle placement in the vein.



Any contaminants residing in the initial ~0.15ml volume of blood (35x a standard 21G needle) are captured in the u-shaped Kurin Lock®.



When the collection bottle is attached, blood flows directly from the vein into the culture bottle through a separate channel.

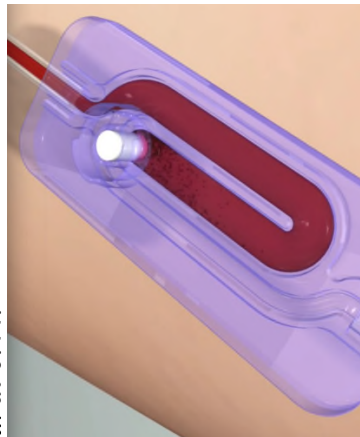
Id. at 681:

Don't give contamination a pass — STICK with Kurin®

When Kurin was used, even hospitals below the 3% benchmark reduced blood culture contamination (BCC) rates by up to 90%* with significant cost savings.

MAG-DEL0000663-670 (K162233 Summary) at 666:

Attachment A

	<p>J. Device Description</p> <p>The Kurin device is a sterile, single use blood culture collection set. The Kurin includes a winged needle with flexible tubing and an attached vial adapter intended for venipuncture to obtain blood culture samples. Kurin is identical in every way to existing sets used to collect blood culture samples except for the insertion into the tubing of the Kurin blood capture chamber. The Kurin blood capture device sequesters the initial draw of blood upon initial venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal. The amount of blood diverted is very small, estimated at a fraction of 1 ml.</p> <p>Below is a table with the three models and sizes of the subject device's that intend to be marketed.</p> <table><tr><th rowspan="2">Model</th><th colspan="3">Measurement (mm)</th><th rowspan="2">Weight (g)</th><th rowspan="2">Tubing</th><th rowspan="2">Gauge</th></tr><tr><th>H</th><th>D</th><th>W</th></tr><tr><td>K-11221</td><td>31mm</td><td>13mm</td><td>6.45mm</td><td>15.7g</td><td>12 in</td><td>21 Gauge</td></tr><tr><td>K-11223</td><td>31mm</td><td>13mm</td><td>6.45mm</td><td>15.7g</td><td>12 in</td><td>23 Gauge</td></tr><tr><td>K-11225</td><td>31mm</td><td>13mm</td><td>6.45mm</td><td>15.7g</td><td>12 in</td><td>25 Gauge</td></tr></table>	Model	Measurement (mm)			Weight (g)	Tubing	Gauge	H	D	W	K-11221	31mm	13mm	6.45mm	15.7g	12 in	21 Gauge	K-11223	31mm	13mm	6.45mm	15.7g	12 in	23 Gauge	K-11225	31mm	13mm	6.45mm	15.7g	12 in	25 Gauge
Model	Measurement (mm)			Weight (g)	Tubing				Gauge																							
	H	D	W																													
K-11221	31mm	13mm	6.45mm	15.7g	12 in	21 Gauge																										
K-11223	31mm	13mm	6.45mm	15.7g	12 in	23 Gauge																										
K-11225	31mm	13mm	6.45mm	15.7g	12 in	25 Gauge																										
<p>a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and</p>	<p>Each of the Accused Products includes a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient. <i>See, e.g.,</i></p> <p>MAG-DEL0000838 (Kurin Video) (“Kurin is a device designed to contain the initial volume of blood from the venipuncture site so that resident contaminants within the skin are not transferred into the blood culture sample.”)</p> <p><i>Id.</i> at 0:44:</p> 																															

Attachment A

	<p>KUR-MAG-DE001632 (IFU_Kurin Blood Culture Collection Set with Kurin Lock™ Technology) (“The Kurin set is a sterile, single-use blood culture collection set. Kurin includes a winged needle with flexible tubing and an attached blood culture bottle holder intended for venipuncture to obtain blood culture samples. The Kurin Lock blood capture device sequesters the initial draw of blood upon venipuncture.”);</p> <p>KUR-MAG-DE002283 (IFU_Kurin PIV12 Blood Culture Collection Set with Kurin® Lock Technology) (“The Kurin PVV12 series of Kurin sets are sterile, single-use blood culture collection sets that include the Kurin Lock, flexible tubing, an attached blood culture bottle holder, and a male luer intended for direct connection to a freshly placed peripheral IV (PIV) catheter to obtain blood culture samples. The Kurin Lock sequesters the initial draw of blood upon first access to the peripheral catheter.”)</p> <p>To the extent the Accused Products do not literally contain a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient, the Accused Products meet this limitation under the doctrine of equivalents because the structures depicted above are equivalent structures that perform a substantially similar function—that is, receiving an initial volume of bodily fluid withdrawn from the patient—in a substantially similar way to achieve a substantially similar result—that is, reducing contamination in the subsequent volume of bodily fluid withdrawn from the patient—as the claimed reservoir.</p>
<p>a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient,</p> <p>the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and</p>	<p>Each of the Accused Products includes a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient. <i>See, e.g.,</i> MAG-DEL0000838 (Kurin Video) at 0:02:</p>

EXHIBIT 4



Fish & Richardson P.C.
1180 Peachtree Street NE, 21st Floor
Atlanta, GA 30309
404 892 5005 main
404 892 5002 fax

September 24, 2019

Corrin Drakulich
Principal
drakulich@fr.com
404 724 2821 direct

VIA EMAIL

Karen Boyd
Turner Boyd LLP
702 Marshall Street, Suite 640
Redwood City, California 94063

Re: Protective Order, Discovery and Case Management Issues (*Magnolia Medical Technologies, Inc. v. Kurin, Inc.*, No. 19-00097-CFC (USDC-DE))

Dear Karen:

I write in response to your letter of September 13, 2019, regarding protective order, discovery and case management issues, and following the parties' discussion of these issues at the September 18, 2019 meet and confer.

I. Protective Order

As you know, Magnolia has been working since July to resolve the asymmetrical nature of the protective order as it pertains to IPR proceedings. The asymmetry *permits* Kurin's counsel in this case to prepare, file and prosecute IPR proceedings against Magnolia's asserted patents and *prevents* Magnolia's counsel in this case from defending those same proceedings. Assuming Kurin files IPR proceedings, the asymmetry would force Magnolia to retain and educate a second set of lawyers to defend the IPR proceedings. Magnolia's IPR lawyers would develop and make the same (or very similar) validity arguments in the IPR proceedings as Fish (Magnolia's litigation counsel) will make in the district court litigation. The financial burden on Magnolia would be substantial.

Kurin's sole basis for maintaining the asymmetry was a concern Magnolia may try to amend its claims in the IPR proceedings (thus invoking patent prosecution concerns). To eliminate Kurin's concern, Magnolia offered to stipulate that it will **not** amend claims of the asserted patents during any IPR proceedings. Magnolia's stipulation resolves Kurin's sole concern. Nonetheless, Kurin has not accepted Magnolia's offer to stipulate, leaving the parties at an impasse.

II. Reduction of Asserted Claims

Magnolia is under no obligation to reduce the number of asserted claims at this early stage of the litigation. The parties have not yet exchanged claim terms for construction, let alone proposed constructions, and resolution on claim construction issues is still months away. As such, the



Karen Boyd

September 24, 2019

Page 2

scope of the asserted claims is subject to change. Moreover, Kurin's failure to provide invalidity contentions that meaningfully disclose Kurin's contentions regarding obviousness and alleged § 112 deficiencies, as explained in our letter of September 5, 2019, has prevented Magnolia from being able to assess the relative strengths and weaknesses of the presently asserted claims.

Nonetheless, in the interest of compromise, Magnolia will drop a substantial number of asserted claims (38 claims) as follows:

- U.S. Pat. No. 9,855,001: Claims 2, 3, 7, and 25
- U.S. Pat. No. 10,028,689: Claims 5, 10, 14, 18, 19, 20, 21, 24, 25, 26, 27, 28
- U.S. Pat. No. 10,039,483: Claims 2, 3, 4, 10, 11, 12, 15, 20, 25, 26, 27
- U.S. Pat. No. 10,220,139: Claims 2, 3, 5, 6, 7, 8, 9, 10, 15, 20, 28

This leaves the following claims as asserted:

- U.S. Pat. No. 9,855,001: Claims 1, 4, 21-23, 26-28
- U.S. Pat. No. 10,028,689: Claims 1-4, 6, 8-9, 11-13, 15, 17, 23
- U.S. Pat. No. 10,039,483: Claims 1, 6, 8-9, 16-19, 21-22, 24
- U.S. Pat. No. 10,220,139: Claims 1, 13-14, 16, 18-19, 21, 23-24, 26-27, 29

We expect that this significant reduction addresses and resolves Kurin's alleged burden and allows it to meaningfully disclose its contentions regarding invalidity.

For example, we expect Kurin to disclose the specific prior art combinations it is relying on for its obviousness contentions, as well as an explanation of why those references would be combined and how said combination would render the claimed invention obvious. *See* Scheduling Order (D.I. 24 at 5) (requiring Kurin to provide in its invalidity contentions "an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness"); *Cephalon, Inc. v. Watson Pharm., Inc.*, 769 F. Supp. 2d 761, 782 (D. Del. 2011) ("[A] defendant asserting obviousness in view of a combination of references has the burden to show that a person of ordinary skill in the relevant field had a reason to combine the elements in the manner claimed." (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007))); *see also Ironworks Patents LLC v. Samsung Elecs. Co.*, 2017 WL 4573366, at *1-*3 (N.D. Cal. 2017) (striking with leave to amend invalidity contentions that did not set forth the specific combination of prior art references relied on to show obviousness).



Karen Boyd
September 24, 2019
Page 3

Similarly, we expect Kurin to disclose the basis for its contentions regarding § 112. As at least one court has explained, “[w]hile the requirements for asserting a written description theory are not as detailed as for a claim of obviousness, it still must meet this threshold of giving the other party sufficient notice for it to engage in meaningful discovery and preparation of its case.” *MediaTek, Inc. v. Freescale Semiconductor, Inc.*, Case No. 11-cv-5341 YGR, 2014 WL 690161, at *6 (N.D. Cal. Feb. 21, 2014) (citing, among other cases, *O2 Micro Intern’l, Ltd. v. Monolithic Power Systems, Inc.*, 467 F.3d 1355 (Fed. Cir. 2006)). Simply stating that a theory of indefiniteness, written description, or enablement is asserted as to a term—as Kurin has done—is plainly insufficient, as it fails to explain—even in the most basic terms—why Kurin contends the term is indefinite or lacking written description or enablement. *See id.* at *6-7.¹

Finally, we cannot agree to the proposal in your September 20, 2019 letter, under which the claim construction process would be delayed by several months. The only basis Kurin offers in support of the delay is its desire for “fulsome” contentions. Magnolia provided Kurin with fulsome contentions on July 17, 2019, the date set forth in the scheduling order. Additionally, Magnolia quickly and repeatedly responded to Kurin’s requests for additional information and detail, including providing additional detail in the attached Exhibit A (*see* discussion below).

III. Magnolia’s Infringement Contentions

In your letter of September 13, 2019, you took issue with the specificity of the location of numerous structural elements identified in Magnolia’s infringement contentions, many of which you challenged for the first time. Magnolia’s contentions more than suffice to put Kurin on notice of Magnolia’s infringement positions. As we have explained, the line drawing exercise Kurin seems to be demanding is premature and unproductive at this early stage of the litigation. As you know, in less than two weeks the parties will be exchanging claim terms and proposed constructions, at which point each side will have a clearer understanding of the other side’s positions regarding the scope of the claims. There has also been limited fact discovery, no expert discovery, and no claim construction order, all of which may impact Magnolia’s infringement contentions. Magnolia will, of course, supplement its contentions accordingly as it is required to do.

¹ We also note that, at the September 18, 2019 meet and confer, counsel for Kurin took the position that Kurin could inject new and undisclosed theories of invalidity and prior art references into this litigation at any time by presenting those new theories and/or references to the PTO, because Kurin had put Magnolia on notice in its invalidity contentions of the possibility of such future proceedings. This position is meritless, and Magnolia will oppose any attempt by Kurin to proceed on previously undisclosed arguments or prior art references under such a theory.



Karen Boyd

September 24, 2019

Page 4

If, by continuing to dispute the adequacy of Magnolia's contentions and demanding that Magnolia commit to the hand-drawn lines, color fill, and annotations in your September 13 letter, Kurin is trying to get Magnolia to prematurely commit to positions so that Kurin can develop its claim construction positions around Magnolia's infringement positions, doing so is improper. Claims are to be construed based on the *intrinsic record*—not the accused device—as the Federal Circuit has explained:

A claim is construed in the light of the claim language, the other claims, the prior art, the prosecution history, and the specification, *not* in light of the accused device. . . . It is only *after* the claims have been *construed without reference to the accused device* that the claims, as so construed are applied to the accused device to determine infringement.

SRI Intern. v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1118 (Fed. Cir. 1985) (en banc) (emphasis in original); *see also NeoMagic Corp. v. Trident Microsystems, Inc.*, 287 F.3d 1062, 1074 (Fed. Cir. 2002) ("It is well settled that claims may not be construed by reference to the accused device.").

Nonetheless, in an attempt to resolve this dispute without the Court's assistance, in Exhibit A to this letter we have attempted to provide even more specificity regarding how the structures in the accused products correspond to the claim terms identified in your September 13, 2019 letter. We trust that this resolves the issue.

Very truly yours,

A handwritten signature in black ink, appearing to read "Corrin Drakulich". The signature is fluid and cursive, with a horizontal line extending from the end.

Corrin Drakulich



Karen Boyd
September 24, 2019
Page 5

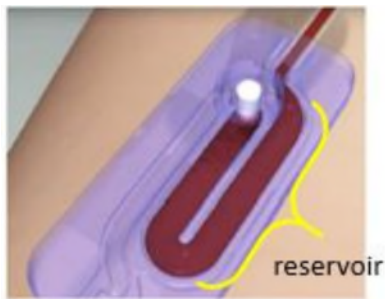
EXHIBIT A

Your September 13, 2019 letter included a number of statements and annotations that you described as laying out your understanding of Magnolia's Infringement Contentions. As we explained at the September 18, 2019 meet and confer, these statements and annotations do not reflect Magnolia's infringement contentions, and Kurin should not "rely on this understanding regarding Magnolia's infringement contentions going forward in this case." Instead, our contentions are fully laid out in Magnolia's infringement contentions and the four exhibits attached thereto, along with the further detail we have attempted to provide below in a good faith effort to resolve this dispute.

That said, this litigation is still in its early stages. The annotations below are based on Magnolia's current understanding of the scope of the claim terms and the operation of the Kurin device. To the extent fact discovery, expert discovery, the parties' proposed constructions, or the Court's claim construction order affects this understanding, Magnolia will supplement its contentions accordingly.

"reservoir," "contaminant reservoir," "fluid reservoir," "internal reservoir," and "internal fluid reservoir"

Independent claims 1 and 21 of the '001 patent, claim 23 of the '689 patent, and claim 18 of the '483 patent recite a "reservoir." As we explained at the September 18, 2019 meet and confer, this reservoir corresponds to at least the "U-shaped side channel" structure, shown in the below annotation. (Magnolia's Infringement Claim Chart, Att. A, at 27-28; *see also id.* at 4-5.)



(MAG-DEL0000838 (Kurin Video) at 0:44.) This "U-shaped side channel" structure also satisfies the "contaminant reservoir" limitation from claims 1, 8, and 17 of the '689 patent, the "fluid reservoir" limitation from claim 1 and 9 of the '483 patent, and the "internal fluid reservoir" limitation from the independent claims of the '139 patent.

At the September 18, 2019 meet and confer, you asked whether these limitations could be grouped together. If you are asking whether these terms should have the same construction, the



Karen Boyd
September 24, 2019
Page 6

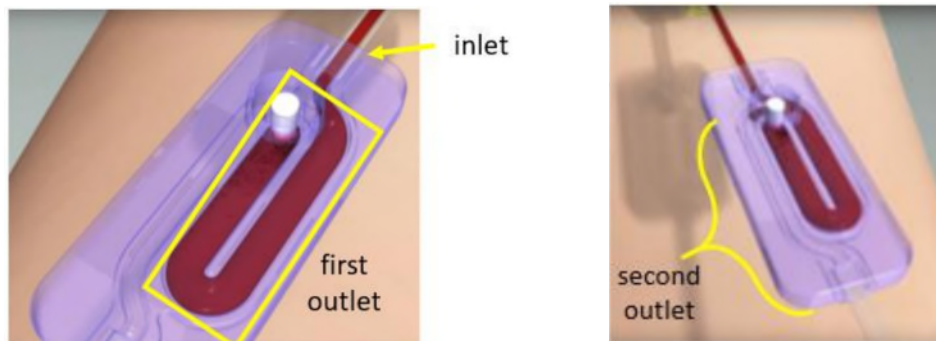
fact that Magnolia has identified the same portion of the Kurin device does not mean these terms are identical in scope. However, we agree that there is significant overlap in these terms and, as such, it may make sense to group them together for the claim construction process, with any differences in claim scope to be addressed individually.

“diverter”

Claims 1, 7, 21, 25, and 28 of the '001 patent and claims 23 and 25-27 of U.S. Pat. No. 10,028,689 (the '689 patent) recite a “diverter.” As shown in Claim Chart A of Magnolia’s Infringement Contentions, Magnolia has identified the Kurin housing in its fully assembled form as satisfying the diverter limitations. For example, at page 33 of Chart A, Magnolia identified the top and bottom housing components, as assembled with the umbrella valve, and the white porous seal, as satisfying the requirement that the diverter “transition from the first operating mode to the second operating mode as a result of the initial volume of bodily fluid flowing from the patient and substantial pressure equalization” (*id.* at 9 (discussing claim 1 of the '001 patent)) and “divert the flow of bodily fluid to the second fluid flow path as a result of receiving the initial volume of bodily fluid from the patient and substantial pressure equalization,” (*id.* at 30-33 (discussing claim 21 of the '001 patent)). (Magnolia’s Infringement Claim Chart, Att. A, at 33.)

“a diverter having an inlet, a first outlet . . . , and a second outlet”

Claim 1 of the '001 patent recites “a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet.” The portions of the accused Kurin devices identified below satisfy the inlet, first outlet, and second outlet limitations, respectively.



(MAG-DEL0000838 (Kurin Video) at 0:44; 0:48.)

We disagree with your characterization of claim 23 of the '689 patent as reciting a diverter having an “inlet,” “first outlet,” and “second outlet.” Instead, as you correctly note on page 8 of your September 13, 2019 letter, this claim recites a “junction including an inlet fluidically

EXHIBIT 5

ATTACHMENT A

CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER

Attachment A - Infringement of U.S. Patent No. 9,855,001

This chart applies the claims of Magnolia's U.S. Patent No. 9,855,001 ("the '001 patent") against Kurin's blood culture collection sets numbered K-11221, K-11223, K-11225, D-11221, D-11223, D-21223, M-11221, M-11223, M-21223, T-11221, T-21221, T-11223, T-21223, D-PIV12, D-PIV18, M-PIV12, M-PIV18, T-PIV12, T-PIV18, S-PIV4, and S-PIV10, (collectively, "the Accused Products").¹

Based on the information Kurin has provided to date, it is Magnolia's understanding that Accused Products K-11221, K-11223, K-11225 are models submitted to the FDA for approval. March 22, 2016 Email Re Kurin Numbering System [KUR-MAG-DE294038]. It is also Magnolia's understanding that one or more of these "K" versions of the Kurin Lock did not include the umbrella valve that is present in the Kurin Lock device that is commercially available today, however, in all other respects those earlier "K" versions that did not include the umbrella valve were the same or substantially similar to the current, commercially available Kurin Lock device.

The Accused Products are substantially similar to one another. D.I. 59 at 4 (Kurin stating that "Magnolia asserted 82 claims – later reduced to 44 – targeting a single Kurin device."). Each of the Accused Products includes a Kurin Lock device. *See, e.g.*, MAG-DE0000688–693 (<https://www.kurin.com/skin-contaminant-diversion/>) at 688 ("The Kurin Lock® - Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful specimen diversion device that automates diversion during the routine process of drawing a blood culture."). Kurin's website includes a "How it Works" page that includes a single animation that purports to describe and depict the operation of the Kurin Blood Collection Set that includes the Kurin Lock device. (<https://www.kurin.com/skin-contaminant-discard/>). The listing of Accused Products is intended to be a list of all commercially available versions of Kurin's blood culture collection sets.

Based on the information presently available to Magnolia, the Kurin Lock device consists of five (5) individual parts. *See* Dkt. 94, Declaration of Jonathan Hangartner in Support of Kurin's Samples of the Accused Product; 2020-07-01 Motion for Leave Hearing Transcript. As described in the Hangartner Declaration, those five components are a top plate, a bottom plate, a cap, an umbrella valve and a porous plug. *Id.* *See also* Kurin Drawing Numbers KUR-2005 (Top Housing) [KUR-MAG-DE001623-24], KUR-2006 (Bottom Housing) [KUR-MAG-DE001625-26], KUR-2007 (Cap) [KUR-MAG-DE001627], KUR-6010 (Hydrophobic Self-Sealing Plug) [KUR-MAG-DE001655], KUR-6011 (Umbrella Valve) [KUR-MAG-DE001656], and KUR-8036 (Assembly) [KUR-MAG-DE001659], MiniValve Part Number UM 053.002 SD (Umbrella Valve and seating suggestion) [KUR-MAG-DE003703];

¹ To the extent Kurin is selling other blood culture collection sets that use the Kurin Lock device, Magnolia accuses those versions as well and the analysis in this chart applies to those versions.

Attachment A

Manufacturing Procedure MP-016 [KUR-MAG-DE000104-124] and the duplicates of these drawings produced throughout KUR-MAG-DE000138-2362. A table (shown below) produced along with Kurin's engineering drawings shows that the same set of engineering drawings is for the Kurin Lock device found in every version of the Accused Product:

top level	D-11221	D-11223	D-21221	D-21223	D-PIV12	D-PIV18	M-11221	M-11223	M-21221	M-21223	M-PIV12	M-PIV18	T-11221	T-11223	T-21221	T-21223	T-PIV12	T-PIV18	S-PIV10
IFU	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
inner box label	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
shipper box label	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
tape	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
inner carton	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
shipper box	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
label	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
packaged device	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
adhesive	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
prod label	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
tray/pouch	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
lid stock	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
collection adapter	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
collection set	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
luer adapter	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
male luer	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
vented cap for male luer	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
tubing	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
extension set	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
cap for female luer	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
lock	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
top housing	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
btm housing	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
cap	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
adhesive	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
lubricant	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
plug	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090
valve	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4076	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090


KUR-MAG-DE0001621 (boxed to show the Kurin Lock device schematics are the same for all Accused Products).

As such, Magnolia contends that, for purposes of the infringement analysis, the Accused Products are identical except where otherwise indicated below. Magnolia reserves its right to amend these contentions as additional information becomes available.

In addition to the exemplary documents provided in the chart, Magnolia also relies on and/or reserves the right to rely on the 510(k) submissions for the Accused Products produced by Kurin at KUR-MAG-DE000137 through KUR-MAG-DE001620, the engineering drawings for the Accused Products produced by Kurin at KUR-MAG-DE001621 through KUR-MAG-DE001869, and Kurin's patent applications describing the Accused Products, including U.S. Patent Appl. Pub. 2018/0271425 [MAG-DEL0000720].

Claim 1	Accused Products
1. An apparatus for obtaining a bodily fluid sample from a	Each of the Accused Products is an apparatus for obtaining a bodily fluid sample from a patient with reduced contamination. <i>See, e.g.,</i>

Attachment A

<p>patient with reduced contamination, the apparatus comprising:</p>	<p>MAG-DEL0000684–687 (https://www.kurin.com/kurin-lock-specimen-diversion-device/) at 684 (“Each Kurin® blood culture collection set features industry-leading butterfly needles and is compatible with all major blood culture bottles. The Kurin blood culture set is enhanced by a Kurin Lock® specimen diversion device enabling clinicians to automatically divert the initial aliquot of blood, which may contain skin microbes, from every draw.”)</p> <p>MAG-DEL0000688–693 (https://www.kurin.com/skin-contaminant-diversion/) at 688 (“The Kurin Lock® - Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful specimen diversion device that automates diversion during the routine process of drawing a blood culture.”)</p> <p>MAG-DEL0000680–681 (Kurin Brochure) at 680:</p> <div data-bbox="669 772 1177 1444">  <p>Blood Culture Collection Sets</p> <p>Traditional blood culture collection methods provide skin microbes a direct line to the culture.</p> <p>Kurin technology diverts the initial aliquot of blood which may contain skin contaminants. Roughly 20% of the microbes present in skin reside deep in the dermis. With venipuncture, contaminants may be dislodged and drawn into blood culture samples leading to high rates of seemingly unavoidable false positives.</p> <p>Standing guard between the venipuncture site and the culture bottle, the Kurin Lock® specimen diversion device corrals blood from the venipuncture site while the clinically relevant blood sample flows into the blood culture bottle.</p> </div> <p><i>Id.</i> (“Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful device that automatically diverts the initial aliquot of blood during the routine process of drawing a blood culture....Any contaminants residing in the initial ~0.15ml volume of blood (35x a standard 21G needle) are captured in the u-shaped Kurin Lock®. When the collection bottle is attached, blood flows directly from the vein into the culture bottle through a separate channel.”)</p>
--	---

Attachment A

Id.:

How does it work?

Each Kurin blood culture collection set features a Kurin Lock[®], a small but powerful device that automatically diverts the initial aliquot of blood during the routine process of drawing a blood culture.



Serves as a flash chamber to provide visual confirmation of proper needle placement in the vein.



Any contaminants residing in the initial ~0.15ml volume of blood (35x a standard 21G needle) are captured in the u-shaped Kurin Lock[®].



When the collection bottle is attached, blood flows directly from the vein into the culture bottle through a separate channel.

Id. at 681:

Don't give contamination a pass — STICK with Kurin[®]

When Kurin was used, even hospitals below the 3% benchmark reduced blood culture contamination (BCC) rates by up to 90%* with significant cost savings.

MAG-DEL0000663-670 (K162233 Summary) at 666:

Attachment A

	<div>J. Device Description</div> <div>The Kurin device is a sterile, single use blood culture collection set. The Kurin includes a winged needle with flexible tubing and an attached vial adapter intended for venipuncture to obtain blood culture samples. Kurin is identical in every way to existing sets used to collect blood culture samples except for the insertion into the tubing of the Kurin blood capture chamber. The Kurin blood capture device sequesters the initial draw of blood upon initial venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal. The amount of blood diverted is very small, estimated at a fraction of 1 ml.</div> <div>Below is a table with the three models and sizes of the subject device's that intend to be marketed.</div> <table><thead><tr><th rowspan="2">Model</th><th colspan="3">Measurement (mm)</th><th rowspan="2">Weight (g)</th><th rowspan="2">Tubing</th><th rowspan="2">Gauge</th></tr><tr><th>H</th><th>D</th><th>W</th></tr></thead><tbody><tr><td>K-11221</td><td>31mm</td><td>13mm</td><td>6.45mm</td><td>15.7g</td><td>12 in</td><td>21 Gauge</td></tr><tr><td>K-11223</td><td>31mm</td><td>13mm</td><td>6.45mm</td><td>15.7g</td><td>12 in</td><td>23 Gauge</td></tr><tr><td>K-11225</td><td>31mm</td><td>13mm</td><td>6.45mm</td><td>15.7g</td><td>12 in</td><td>25 Gauge</td></tr></tbody></table>	Model	Measurement (mm)			Weight (g)	Tubing	Gauge	H	D	W	K-11221	31mm	13mm	6.45mm	15.7g	12 in	21 Gauge	K-11223	31mm	13mm	6.45mm	15.7g	12 in	23 Gauge	K-11225	31mm	13mm	6.45mm	15.7g	12 in	25 Gauge
Model	Measurement (mm)			Weight (g)	Tubing				Gauge																							
	H	D	W																													
K-11221	31mm	13mm	6.45mm	15.7g	12 in	21 Gauge																										
K-11223	31mm	13mm	6.45mm	15.7g	12 in	23 Gauge																										
K-11225	31mm	13mm	6.45mm	15.7g	12 in	25 Gauge																										
a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and	<div>Each of the Accused Products includes a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient. See, e.g.,</div> <div>The Court construed the term “initial volume” (D.I. 75 at 2):</div> <table><tr><td>“initial volume”</td><td>“the initial portion of blood removed from the patient and sequestered”</td></tr><tr><td>#001 Patent: claims 1, 4, 21-23</td><td></td></tr><tr><td>#483 Patent: claims 1, 8, 9, 24</td><td></td></tr><tr><td>#139 Patent: claims 1, 13, 19, 23, 27</td><td></td></tr></table> <div>MAG-DEL0000838 (Kurin Video) (“Kurin is a device designed to contain the initial volume of blood from the venipuncture site so that resident contaminants within the skin are not transferred into the blood culture sample.”)</div> <div>Id. at 0:44 (annotated):</div>	“initial volume”	“the initial portion of blood removed from the patient and sequestered”	#001 Patent: claims 1, 4, 21-23		#483 Patent: claims 1, 8, 9, 24		#139 Patent: claims 1, 13, 19, 23, 27																								
“initial volume”	“the initial portion of blood removed from the patient and sequestered”																															
#001 Patent: claims 1, 4, 21-23																																
#483 Patent: claims 1, 8, 9, 24																																
#139 Patent: claims 1, 13, 19, 23, 27																																

Attachment A



KUR-MAG-DE001632 (IFU_Kurin Blood Culture Collection Set with Kurin Lock™ Technology) (“The Kurin set is a sterile, single-use blood culture collection set. Kurin includes a winged needle with flexible tubing and an attached blood culture bottle holder intended for venipuncture to obtain blood culture samples. The Kurin Lock blood capture device sequesters the initial draw of blood upon venipuncture.”);

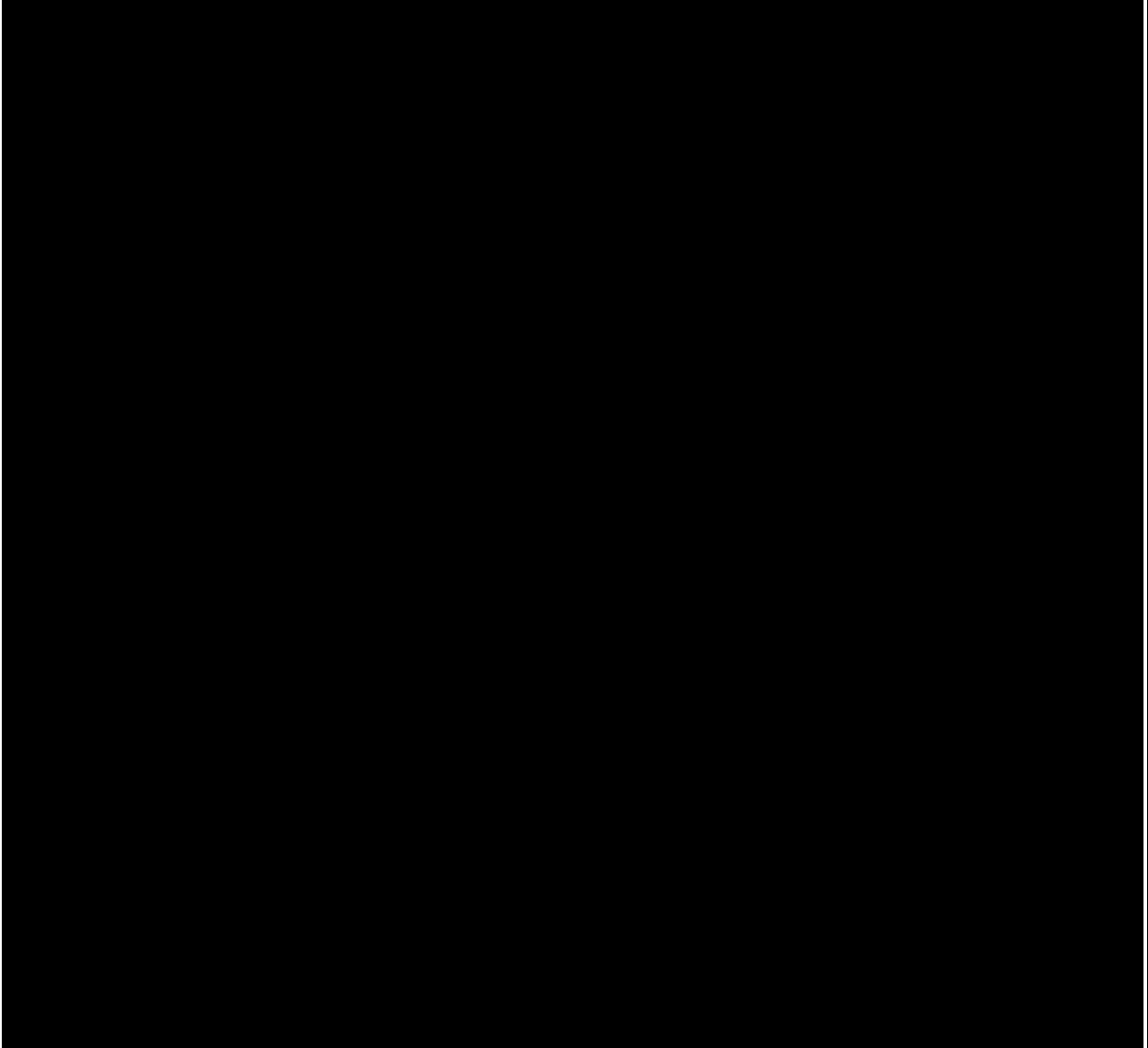
KUR-MAG-DE002283 (IFU_Kurin PIV12 Blood Culture Collection Set with Kurin® Lock Technology) (“The Kurin PIV12 series of Kurin sets are sterile, single-use blood culture collection sets that include the Kurin Lock, flexible tubing, an attached blood culture bottle holder, and a male luer intended for direct connection to a freshly placed peripheral IV (PIV) catheter to obtain blood culture samples. The Kurin Lock sequesters the initial draw of blood upon first access to the peripheral catheter.”)

KUR-MAG-DE450383 (emails between John Detloff, Lonnie Pogue, Bob Rogers, and Gino Kang) (“Also, we need to come up with a maximum reservoir diameter which will still give us laminar flow all the way to the filter.”)

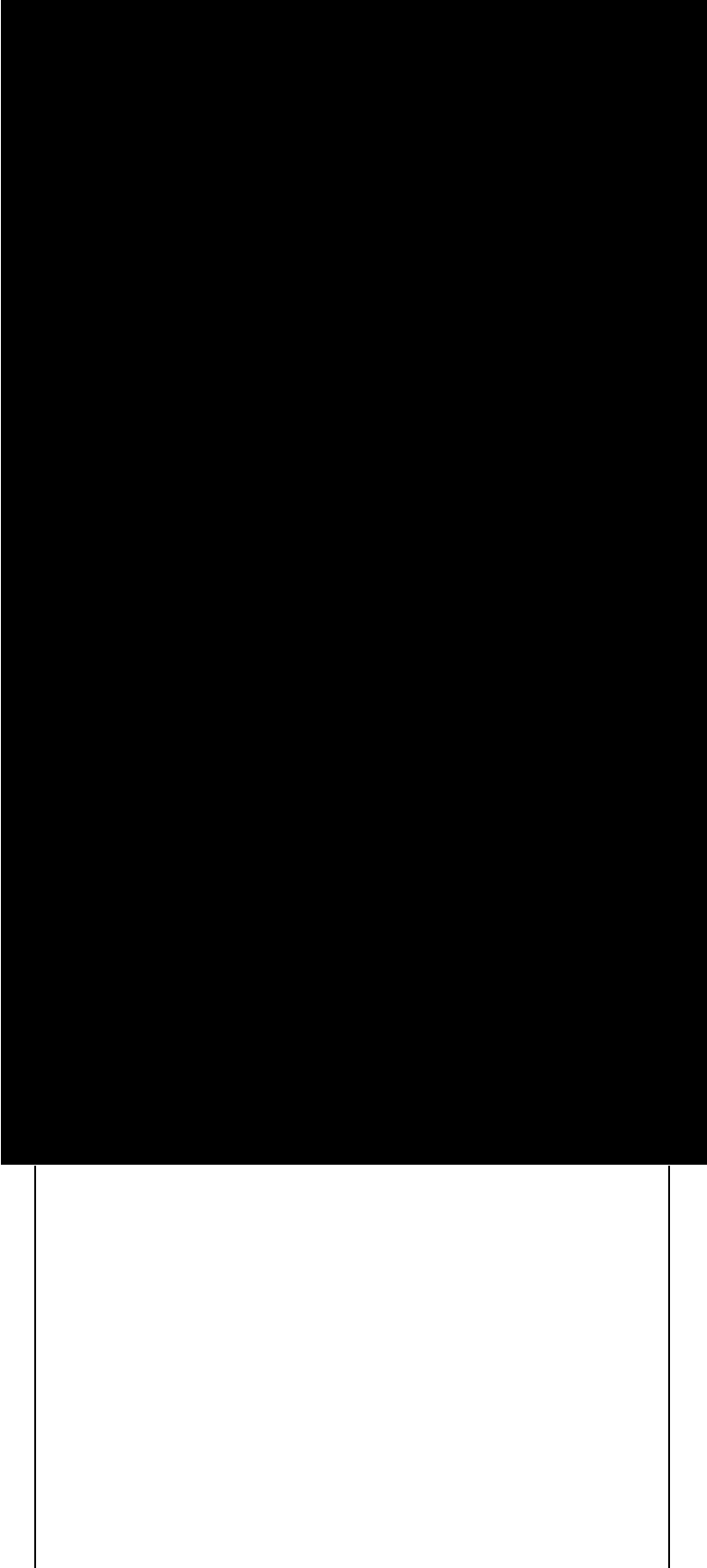
To the extent the Accused Products do not literally contain a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient, the Accused Products meet this limitation under the doctrine of equivalents because the structures depicted above are equivalent structures that perform a substantially similar function—that is, receiving an initial volume of

<p>a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet.</p>	<p>bodily fluid withdrawn from the patient—in a substantially similar way to achieve a substantially similar result—that is, reducing contamination in the subsequent volume of bodily fluid withdrawn from the patient—as the claimed reservoir. Any purported differences between the Accused Products and the claim limitation are insubstantial, and thus the Accused Products are equivalent and therefore infringe.</p>				
<p>a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet.</p>	<p>Each of the Accused Products includes a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet. <i>See, e.g.</i>, The Court construed the term “diverter” to be a means-plus-function term (D.I. 75 at 2):</p> <table border="1" data-bbox="743 420 1068 1451"> <tr> <td data-bbox="743 940 812 1451"> <p>“diverter”</p> </td><td data-bbox="812 940 1068 1451"> <p>#001 Patent: claims 1, 21, 28</p> </td></tr> <tr> <td data-bbox="743 420 812 940"> <p>Means-plus-function</p> </td><td data-bbox="812 420 1068 940"> <p>Function: to divert (or direct) fluid flow from one fluid flow path to a second fluid flow path</p> <p>Structure: an inlet, at least two outlets, and either a switchable valve or flow control blocks</p> </td></tr> </table> <p>The Kurin Lock device literally infringes this limitation because it performs the identical function using identical structures. Alternatively, the Kurin Lock device literally infringes this limitation because it performs the identical function using equivalent structures.</p> <p><u>Function</u></p> <p>The Kurin Lock device diverts (or directs) fluid from one fluid flow path to a second fluid flow path as shown by at least the following:</p>	<p>“diverter”</p>	<p>#001 Patent: claims 1, 21, 28</p>	<p>Means-plus-function</p>	<p>Function: to divert (or direct) fluid flow from one fluid flow path to a second fluid flow path</p> <p>Structure: an inlet, at least two outlets, and either a switchable valve or flow control blocks</p>
<p>“diverter”</p>	<p>#001 Patent: claims 1, 21, 28</p>				
<p>Means-plus-function</p>	<p>Function: to divert (or direct) fluid flow from one fluid flow path to a second fluid flow path</p> <p>Structure: an inlet, at least two outlets, and either a switchable valve or flow control blocks</p>				

Attachment A



Attachment A



Attachment A

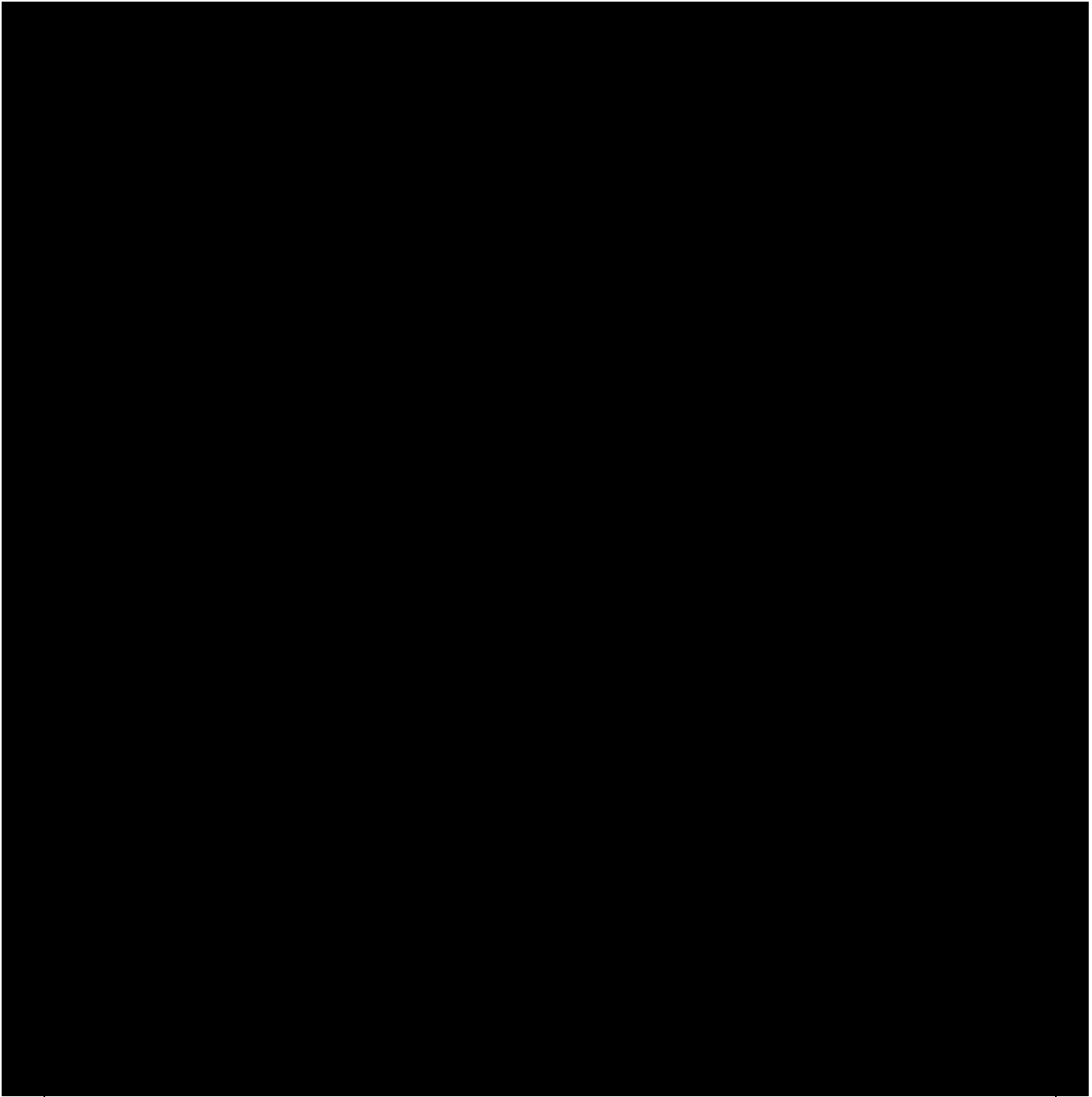


EXHIBIT 6

FILED UNDER SEAL

EXHIBIT 7

FILED UNDER SEAL

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 19-00097-CFC

CONFIDENTIAL

OPENING EXPERT REPORT OF DR. JUAN G. SANTIAGO
REGARDING INFRINGEMENT OF U.S. PATENT NOS. 9,855,001
AND 10,039,483

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. My Own Testing

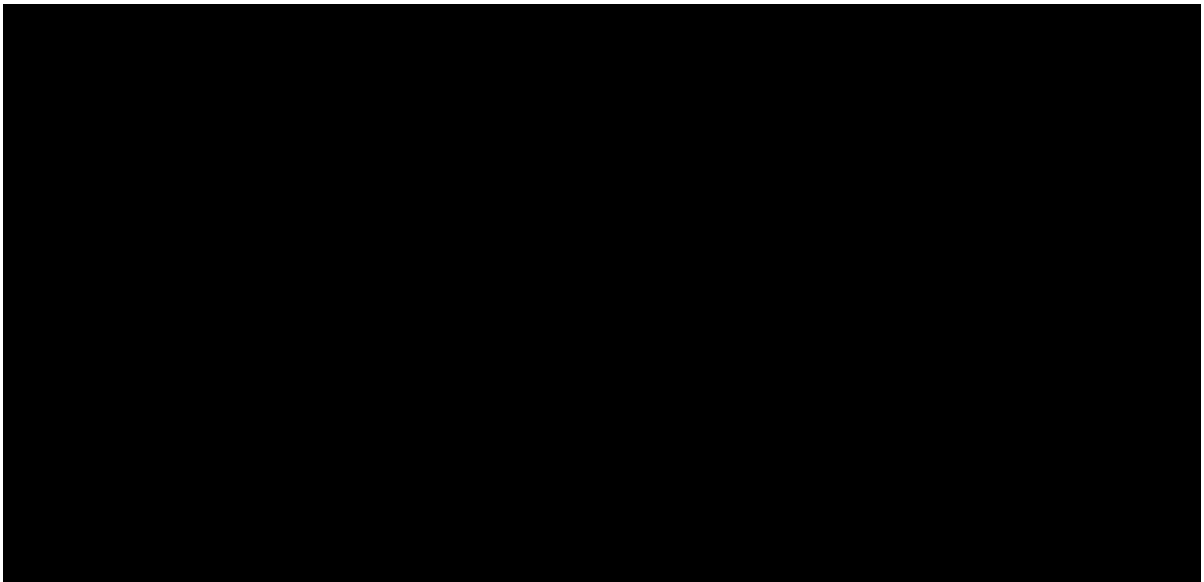
75. In September 2020, I performed my own tests on the accused Kurin Lock devices.

a. Testing Setup

76. I performed a series of tests visualizing fluid flow and mixing in Kurin Lock devices. The working fluid in my tests was a blood analog solution

[REDACTED]

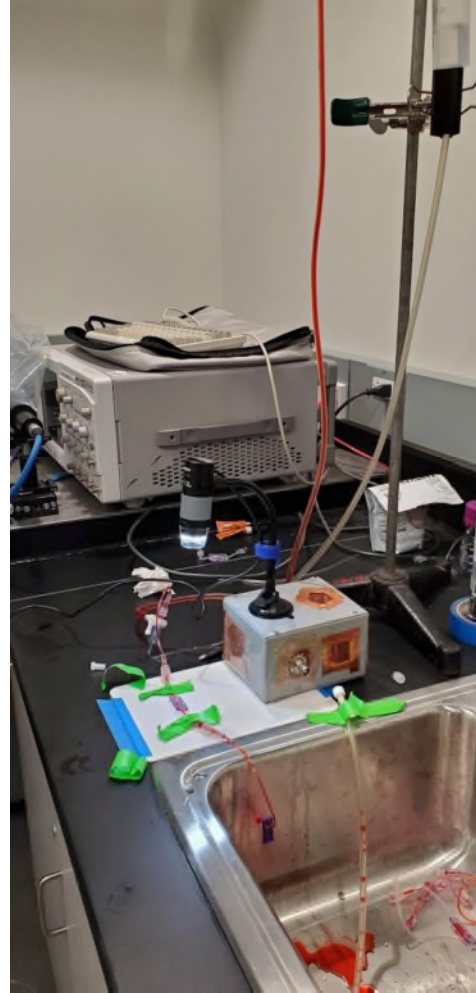
[REDACTED] This blood analog liquid consisted of 600 g of water, 400 g of glycerin, and 0.4 g of xanthan gum.



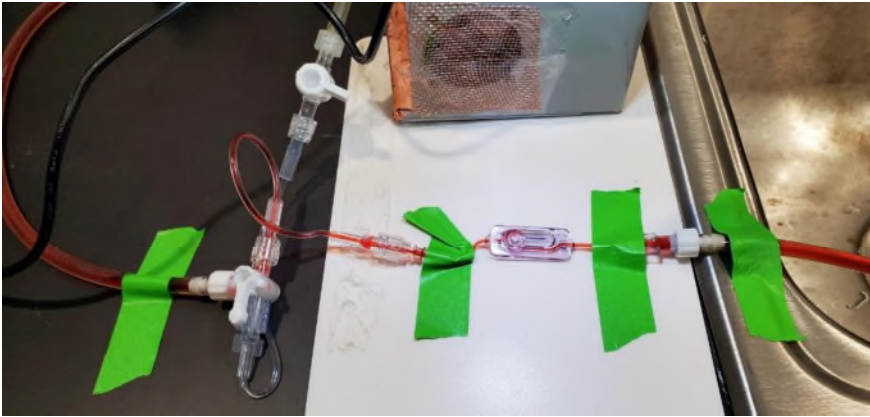
[REDACTED].

77. From this stock, I aliquoted about 400 g of this solution and mixed this aliquot with red food dye to enable visualization of mixing between the clear and dyed blood analog liquids. The tests used two elevated reservoirs connected to flexible polymer tubing to drive flow through various Kurin devices.

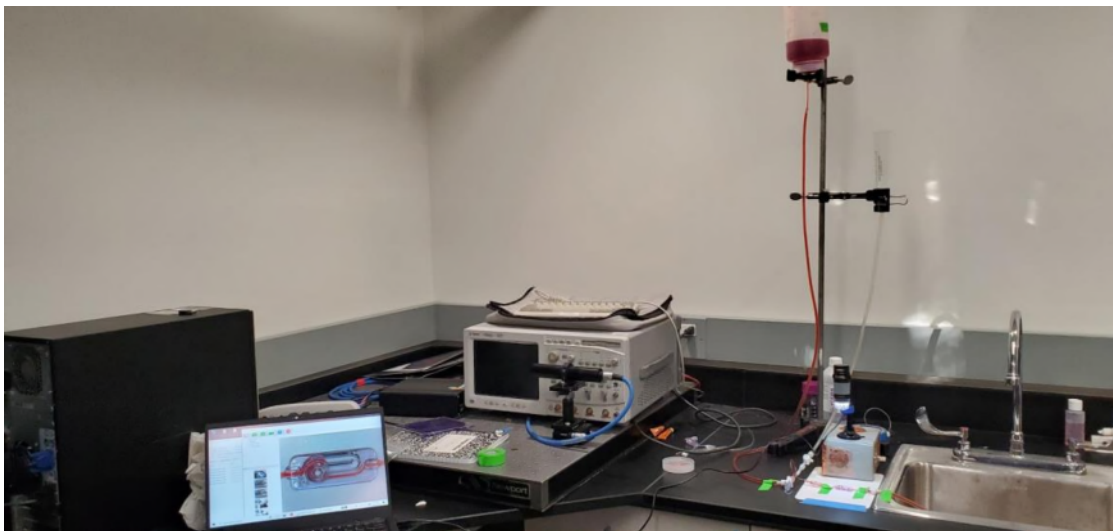
78. Images of my test setup are shown below:



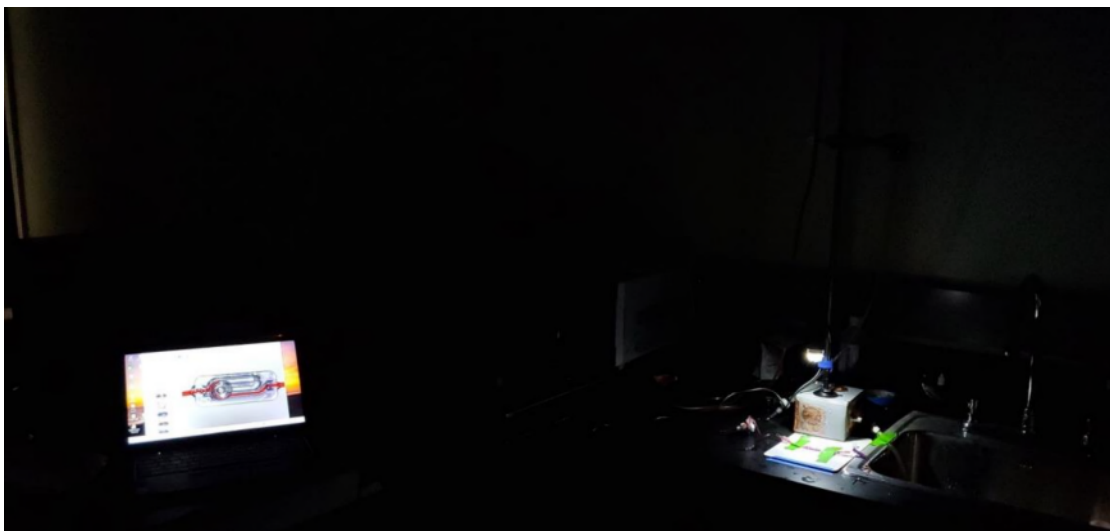
MAG-DEL0826809; MAG-DEL0826811. I secured the devices to a plate with tape and used valves to control the introduction of liquid into the device:



MAG-DEL0826812; MAG-DEL0826813. I used a microscope camera to record videos of the devices in operation:

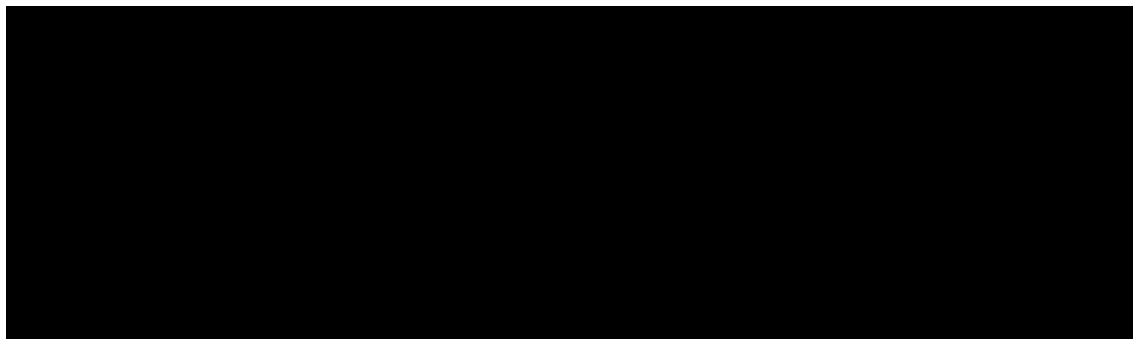


MAG-DEL0826808. I turned out the room lights and used the microscope light to reduce glare and ambient light wash out:



MAG-DEL0826810.

79. A first reservoir was used to supply the main flow rate through the Kurin device and had a free surface elevated by about 90 cm. The second reservoir supplied the initial very small volume of liquid (to the sequestration reservoir) and had a free-surface elevation of 70 cm. The 90 cm height of the main reservoir was selected to provide a hydrostatic head consistent with about 43 g/min flow rate of water through the setup. The blood analog flow rate with this setup was about 20 g/min. These flow rates are therefore [REDACTED]:



80. The outlet tubing of one reservoir passed through a quarter-turn shut off valve and then connected to one of two inputs of a three-way valve. The outlet tubing of the second reservoir connected directly to the second input of the three-way valve. The settings of these two valves allowed connection of one reservoir at a time and allowed shutting off of flow from both reservoirs. The input of each Kurin device was connected to the output of the three-way valve. In turn, the output of the Kurin device was connected to outlet tubing which emptied into a lab sink.

81. The output of each Kurin device was attached to one of three types of outlet tubing. The first outlet tubing length was about 32 cm with a tube inner diameter of about 4 mm. The second outlet tubing had an inner diameter of 1.5 mm and was 40 cm long. The third outlet tubing had an inner diameter of about 1.5 mm and was 10 cm long. The three configurations resulted in what I will here define as small, medium, and large output tubing air volumes. These outlet tubing lengths were typically sealed during the initial filling of the Kurin device (i.e. the initial filling of simulated “contaminated” blood analog). For the large downstream air space, the downstream air volume was sufficiently compressed by the initial liquid fill such that liquid filled the sequestration reservoir, the outlet channel of the Kurin device, and part of the output tubing. That is, for sufficiently

large downstream volume, the entire internal volume of channels of the Kurin device was filled during the initial filling step even when the downstream tubing was sealed. For the medium downstream air space, the Kurin sequestration reservoir filled with liquid and also filled most of the device (i.e. the meniscus stopped near the exit of the device). For the smallest volume, the initial liquid flow filled the Kurin sequestration reservoir and the outlet liquid filled only some fraction of the outlet channel within the device (so that some air remained in the device output channel).

82. In most tests, I first flowed dyed blood analog (filling the sequestration reservoir) and then flowed clear blood analog. In all but one test, the output tubing was sealed during the initial flow of liquid into the Kurin device. For the latter cases, I then switched the valve positions to seal off the initial liquid reservoir, switched to the second liquid reservoir, and then opened the downstream seal to allow flow and mixing. I typically visualized mixing for multiple minutes before ending the testing.

83. The clear and dyed blood analog liquids show qualitatively the degree of mixing between the sequestered liquid in the reservoir and the subsequent liquid injected into the device. These two volumes of liquid show a minimal degree of mixing in the region near the Y-junction. This is observable in the videos. This region of mixing is limited to within about 6 mm from the Y-junction for the first 3

minutes of each run. The spatial extent of the mixing region grows very slowly. For example, for runs in excess of 9 minutes (e.g. consistent with a total of about 180 mL² of blood analog transferred through and collected from the Kurin device) the mixing region is less than about 9 mm from the Y-junction. The majority of the volume of liquid and solute species in the reservoir remain sequestered.

84. Movies were captured using a microscope integrated with an LED array light source and a color CMOS camera (Plugable USB2-MICRO-250X) and a ThinkPad Windows 10 laptop. Movies were saved as .AVI files and were not edited. A few images of the experimental setup were obtained using a Galaxy S10 phone.

b. Testing Videos

85. I performed five tests using the accused Kurin Lock device as intended (i.e., with the downstream volume initially sealed), and these are identified in the table below:

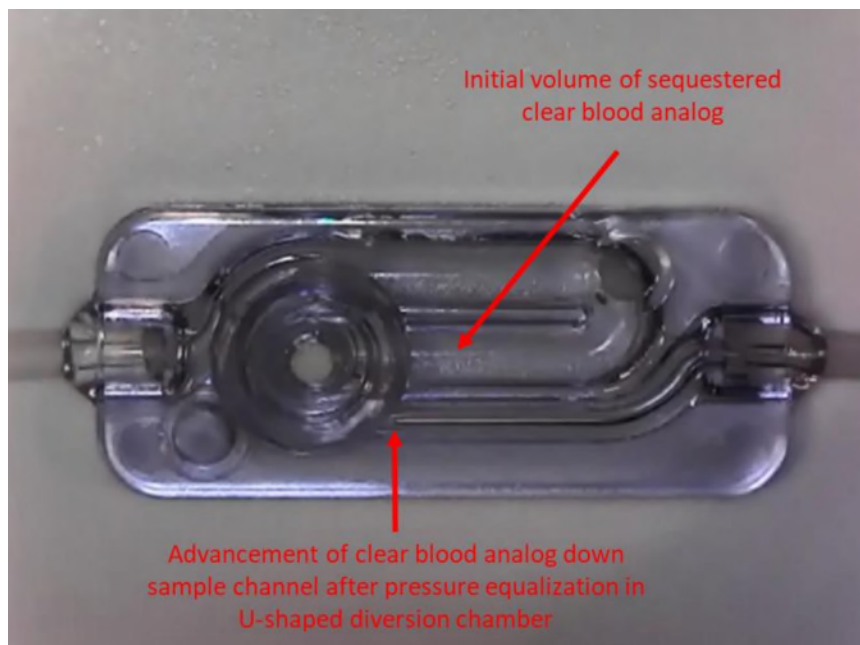
Test Video	Color Flow Order	Downstream Volume	Flow Rate
#1 (MAG-DEL0826804)	Clear/red	Tubing: $\varnothing = 1.5$ mm, length = 10 cm (small)	~20 g/min

² This amount is more than what Kurin uses as a best practice for sample blood collection, which is approximately 32-40 mL of blood in total from the patient.

This means that the tests were run much longer than the device would be used in practice, ensuring that the maximum of mixing was observed in testing.

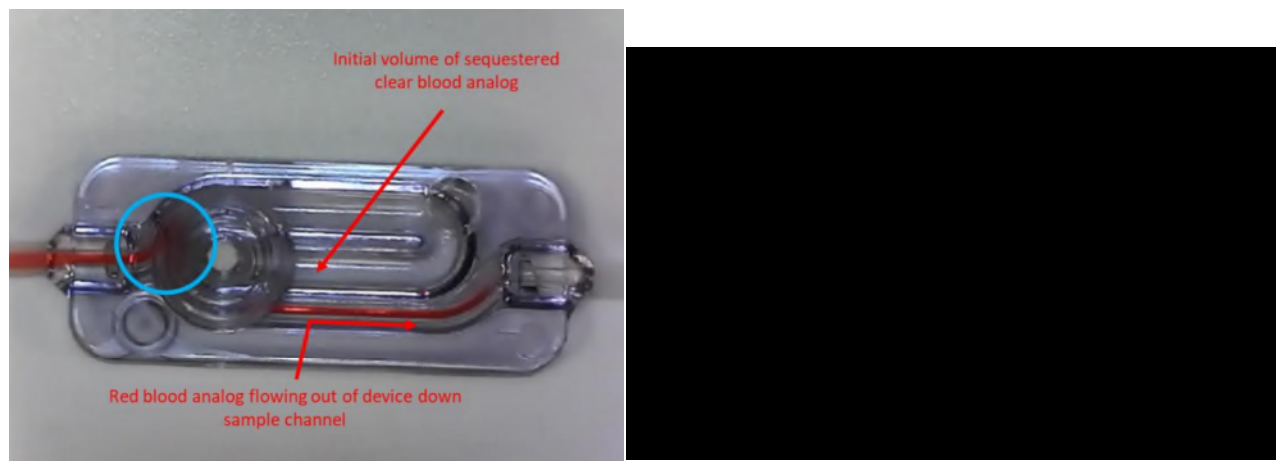
#2 (MAG-DEL0826803)	Red/clear	Tubing: $\varnothing = 1.5$ mm, length = 40 cm (medium)	~ 20 g/min
#3 (MAG-DEL0826805)	Clear/red	Tubing: $\varnothing = 4$ mm, length = 32 cm (large)	~ 20 g/min
#4 (MAG-DEL0826806)	Clear/red/clear	Tubing: $\varnothing = 1.5$ mm, length = 10 cm (small)	~ 20 g/min
#5 (MAG-DEL0826807)	Clear/red	Tubing: $\varnothing = 1.5$ mm, length = 10 cm (small)	$\sim < 1$ g/min

86. **Test #1** – The U-shaped diversion chamber was primed with clear blood analog. After substantial pressure equalization in the U-shaped diversion chamber, ensuing clear blood analog advanced a certain distance down the sample channel:

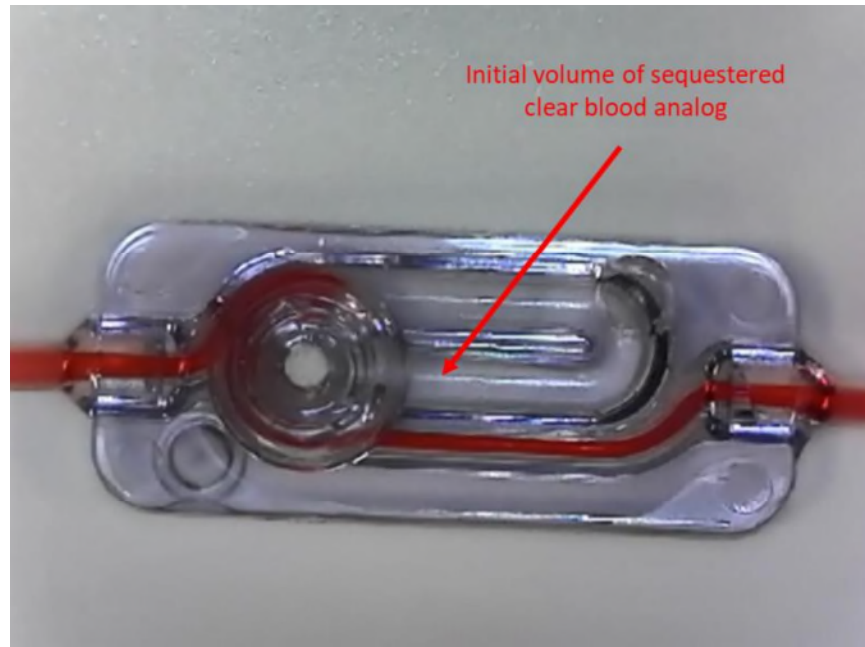


Test #1 – 30.79s (annotated). Due to the relatively small downstream volume, the clear blood analog advanced only a short distance along the sample channel and until pressure equalized in the sample channel. At approximately 59 seconds into

the video, the downstream seal was opened, red blood analog was introduced, and the red blood analog began to flow down the sample path to exit the device:

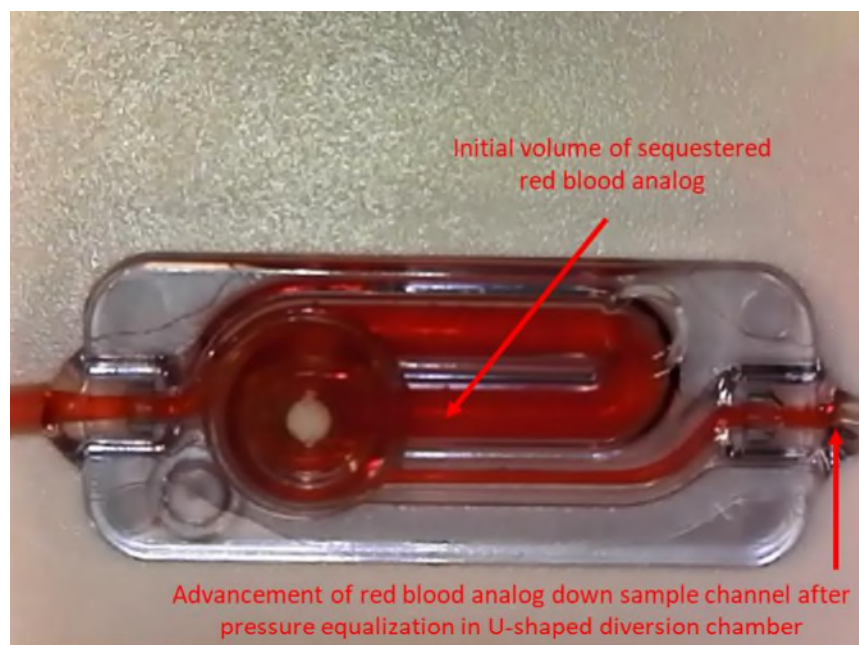


Test #1 – 59.63s (annotated); [REDACTED] Note that the concave-downward curve (blue circle) of the red blood interface does not necessarily indicate mixing and is determined in large part by the shape of streamlines of the flow (i.e. fluid flow paths) within this highly three-dimensional region. After more than 7 minutes of recording, a small amount of the red dye has flowed and diffused into the U-shaped diversion chamber. However, the vast majority of the clear blood analog has remained sequestered in the U-shaped diversion chamber, including the initial volume of clear blood analog:

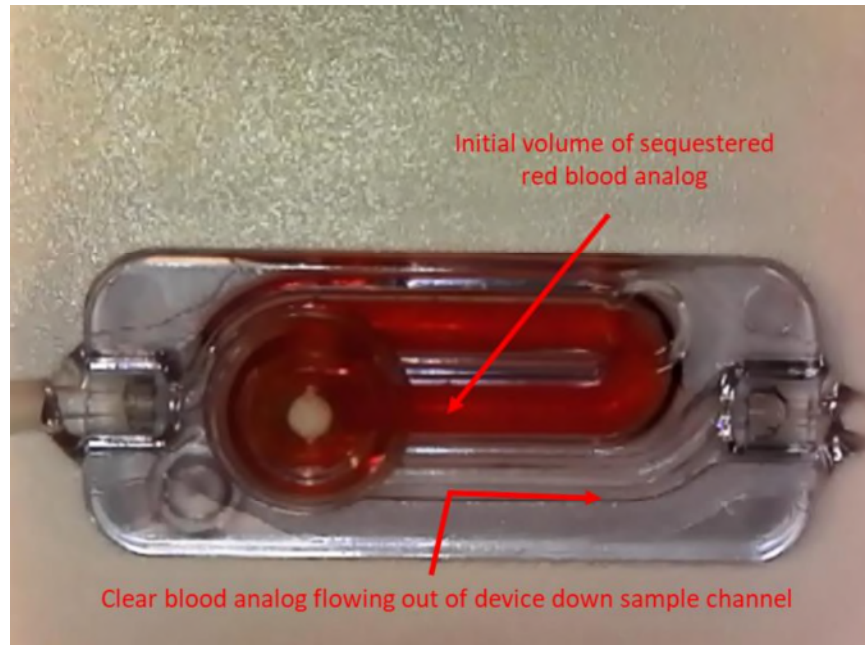


Test #1 – 7min, 41.79s (annotated).

87. **Test #2** – The U-shaped diversion chamber was first primed with red blood analog. After substantial pressure equalization in the U-shaped diversion chamber, the red blood analog advanced a certain distance down the sample channel:



Test #2 – 32.96s (annotated). This test was performed with a medium downstream volume, and red blood analog advanced a distance down the sample channel until pressure approximately equalized in the sample channel. The meniscus stops near the outlet of the Kurin device. At approximately 1 minute into the video, the downstream seal was opened, clear blood analog was introduced, and the clear blood analog flowed down the sample path and to the exit of the device. After more than 2 minutes of recording, a small amount of the clear blood analog can be observed within the U-shaped diversion chamber (and near the Y-junction). However, the vast majority of the red blood analog has remained sequestered within the U-shaped diversion chamber, including an initial volume of red blood analog:

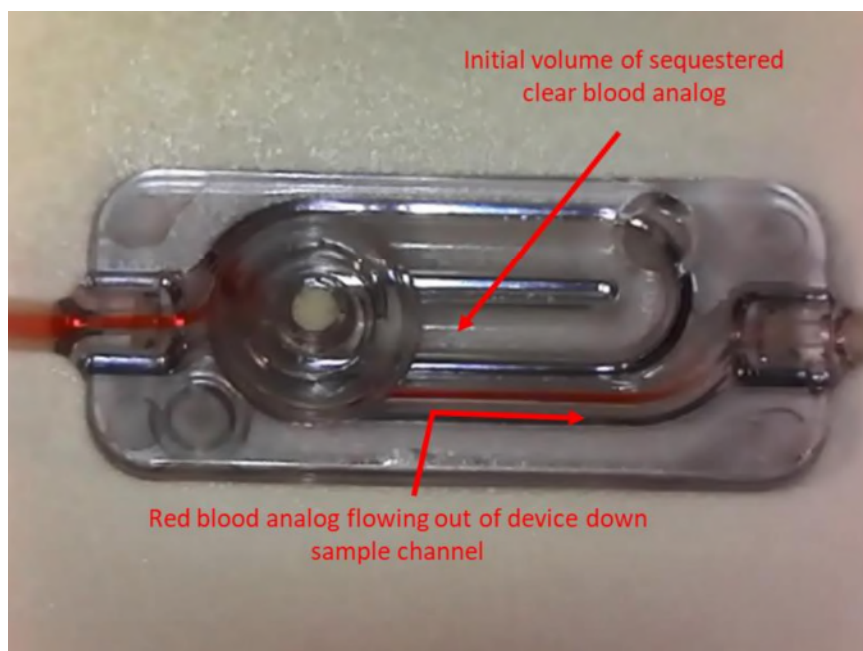


Test #2 – 2min, 34.52s (annotated).

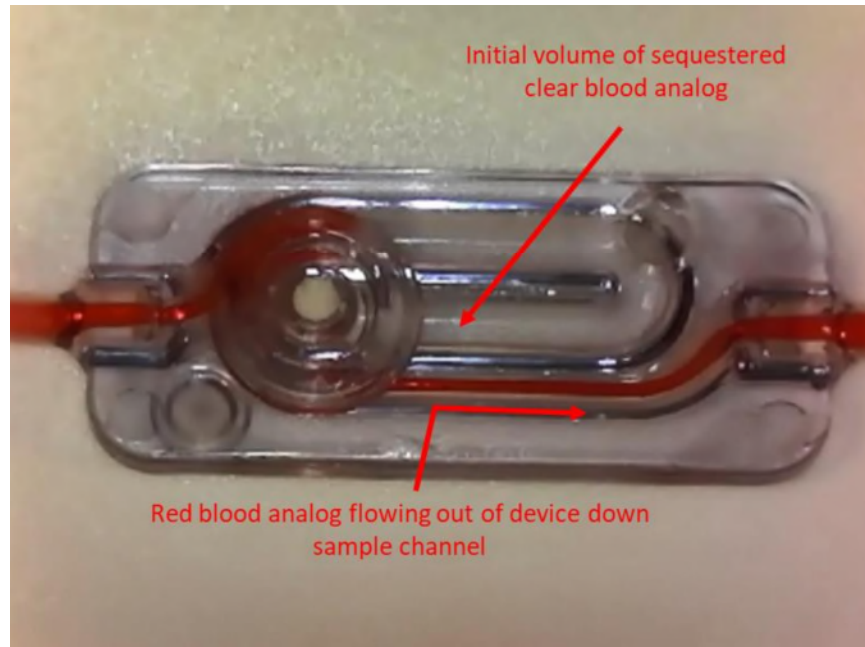
88. **Test #3** – In this test, the U-shaped diversion chamber was primed with clear blood analog. After substantial pressure equalization in the U-shaped diversion chamber, clear blood analog advanced down the sample channel:



Test #3 – 18.96s (annotated). Consistent with the relatively large downstream volume used in this test, the clear blood analog advanced down the sample channel until pressure equalized within the downstream volume. At approximately 1 minute, 31 seconds into the video, the downstream seal was opened, red blood analog was introduced, and the red blood analog flowed down the sample path to exit the device:

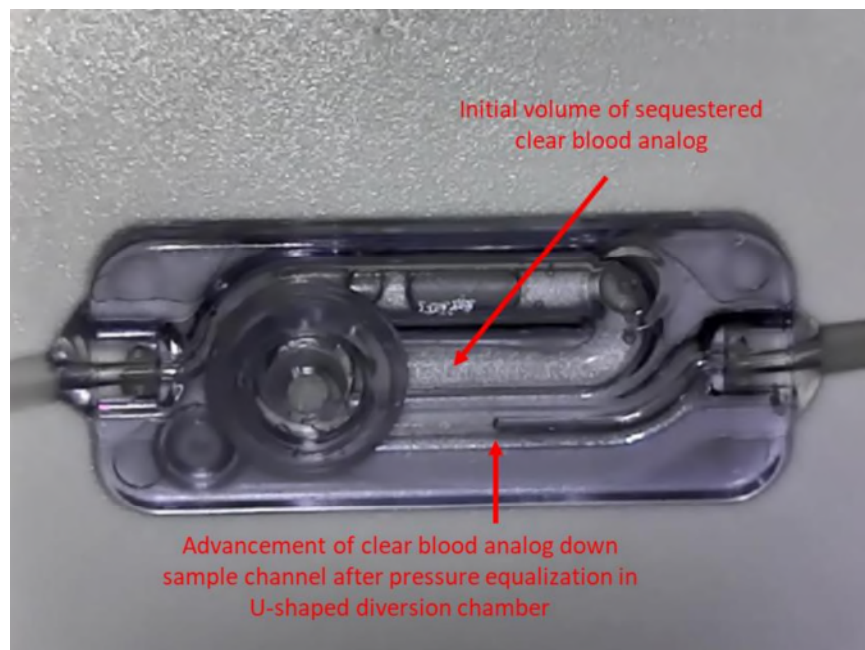


Test #3 – 1min, 31.72s (annotated). After more than 6 minutes of recording, a small amount of the red dye has diffused and flowed into the U-shaped diversion chamber. However, the vast majority of the clear blood analog has remained sequestered in the U-shaped diversion chamber, including the initial volume of clear blood analog:

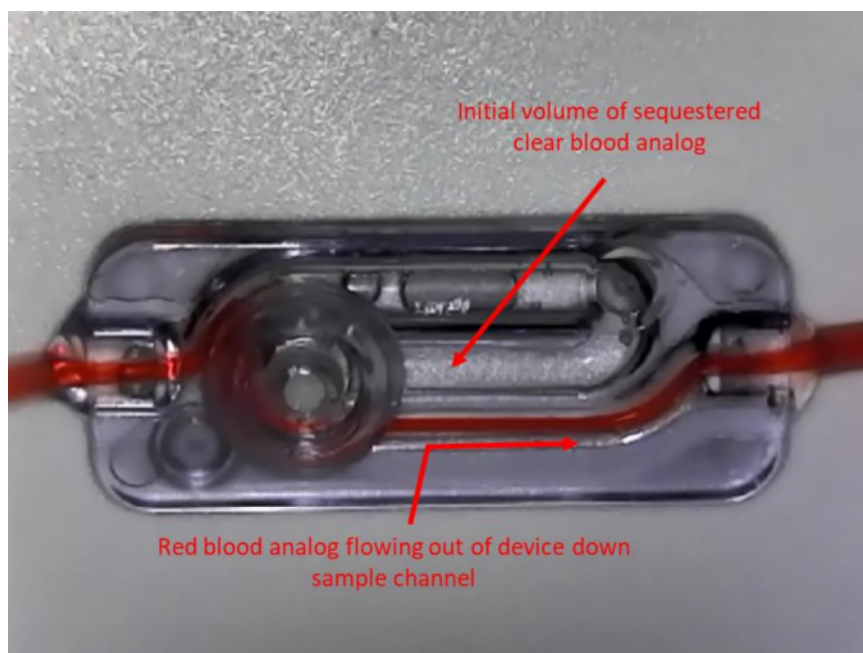


Test #3 – 6min, 01.79s (annotated).

89. **Test #4** – Here, the U-shaped diversion chamber was primed with clear blood analog. After pressure equalization in the U-shaped diversion chamber, clear blood analog advanced down the sample channel:

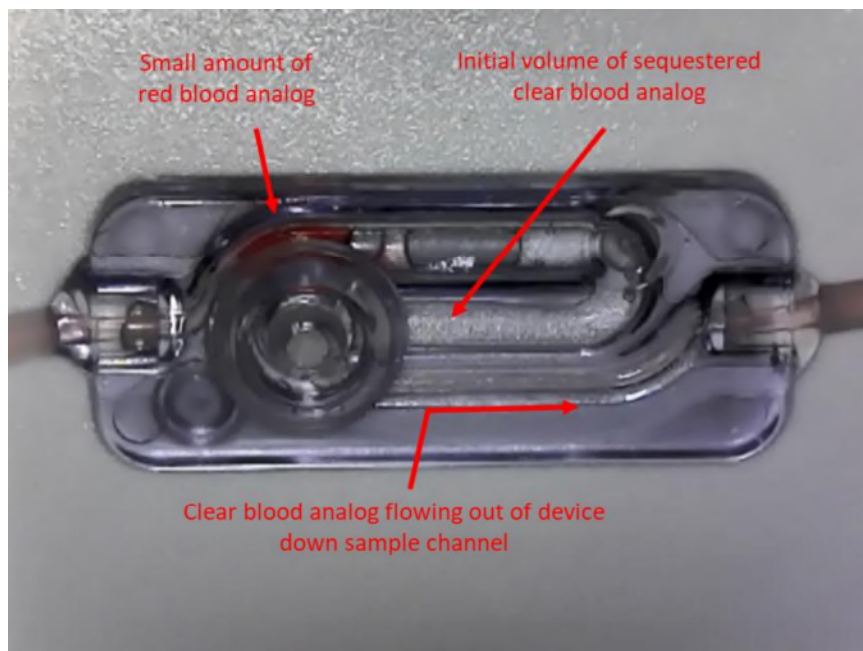


Test #4 – 55.68s (annotated). Consistent with the relatively small downstream volume used here, the clear blood analog advanced a short distance down the sample channel until pressure approximately equalized in the sample channel. At approximately 1 minute, 8 seconds into the video, the downstream seal was opened, red blood analog was introduced, and the red blood analog flowed down the sample path to exit the device:



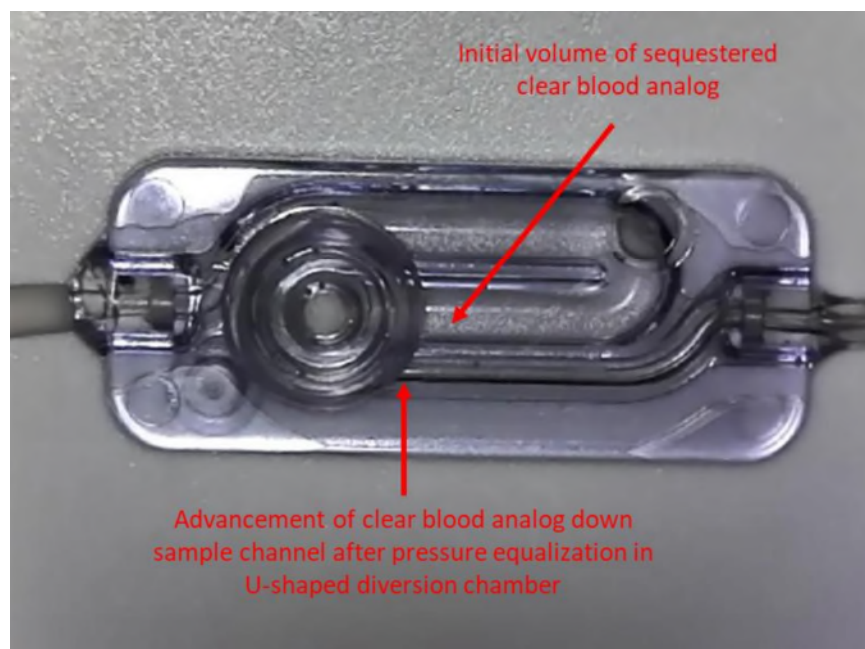
Test #4 – 1min, 36.59s (annotated). Note that, in this test, there are (inadvertent) air bubbles trapped within the U-shaped diversion chamber. These air bubbles are not displaced by or entrained into the red blood analog flow; nor are these air bubbles displaced toward the umbrella valve structure. Instead, they remain sequestered within the U-shaped diversion chamber. At approximately 3 minutes,

15 seconds, clear blood analog was reintroduced, and the clear blood analog flowed down the sample path to exit the device:

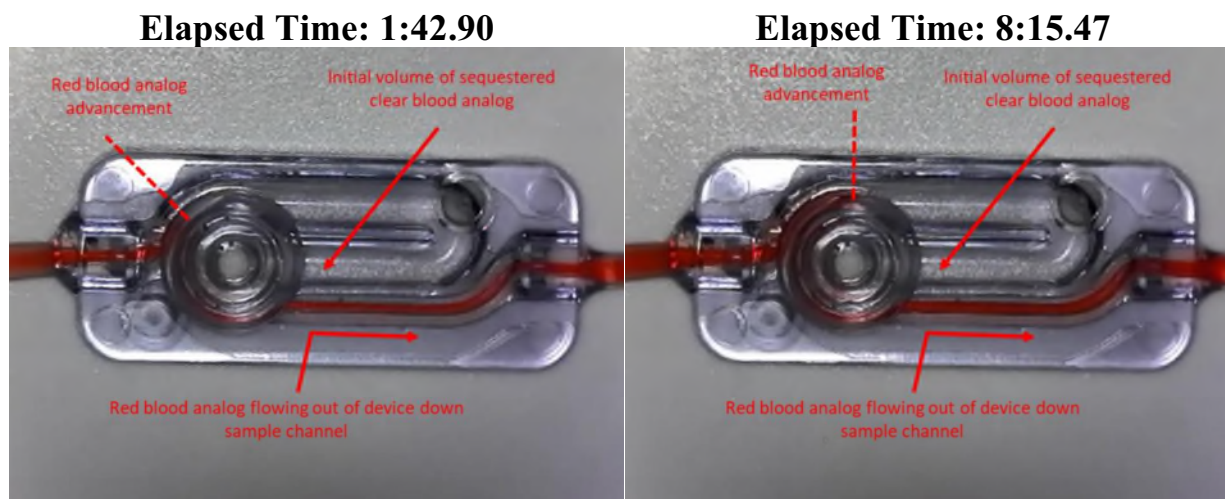


Test #4 – 4min, 10.34s (annotated). After these events, a small amount of red dye (consistent with the presence of red blood analog) remains within the sideline channel. However, the volume of dye-containing liquid is small compared to the volume of clear sequestered blood analog. Also, this dye-containing liquid has negligible effect on the volume of (clear) blood analog which subsequently enters the Kurin Lock bypassing the sequestered blood and exiting the device.

90. **Test #5** – This test was similar to Test #1 but with a slower flow rate. The U-shaped diversion chamber was primed with clear blood analog. After substantial pressure equalization in the U-shaped diversion chamber, clear blood analog advanced a certain distance down the sample channel:



Test #5 – 1min, 24.91s (annotated). Consistent with this test’s relatively small downstream volume, the clear blood analog advanced a short distance down the sample channel until pressure approximately equalized in the sample channel. At approximately 1 minute, 40 seconds into the video, the downstream seal was opened, red blood analog was introduced, and the red blood analog flowed down the sample path to exit the device. After more than 8 minutes of recording, a very small amount of the red blood dye has flowed and diffused into the U-shaped diversion chamber. However, the vast majority of the clear blood analog has remained sequestered in the U-shaped diversion chamber, including the initial volume of clear blood analog:



Test #5 – 1min, 42.90s (left, annotated); Test #5 – 8min, 15.47s (right, annotated).

91. Although my tests show that some of the subsequent, differently colored blood analog enters the diversion chamber, it does not change the fact that there is a subsequent volume of blood analog that completely bypasses the diversion chamber. It also does not change the fact that there is an initial volume of blood analog that stays completely sequestered within the diversion chamber.

92. The Accused Products sequester an initial volume of blood in the U-shaped diversion chamber and a subsequent volume of bypasses the U-shaped diversion chamber into the sample channel to be collected in a sample bottle. To the extent that some mixing occurs in the proximity of the Y-junction, there is nonetheless an initial volume of blood that remains sequestered within the U-shaped diversion chamber and a subsequent volume of blood that bypasses this initial volume sequestered in the diversion chamber.

4 Q. And you said that one of the reasons
5 you wanted them was you wanted to see what the
6 product is supposed to do.

7 What was your understanding, once
8 you educated yourself, of what the Kurin Lock is
9 supposed to do?

10 MR. HANGARTNER: Objection. You can
11 go ahead and answer.

12 THE WITNESS: So, the device is
13 intended for blood collection. The goal is
14 to reduce contamination in blood collection.

15 And it achieves that by, my
16 understanding is it is sort of a waste tube
17 process.

18 It collects the first volume of
19 blood that may have contaminants in one
20 portion, and then allows the rest of the
21 collection to go into the collection vial, to
22 reduce potential contaminations in a vial.

Page 41

1 BY MS. BROOKS:

2 Q. And I'm sorry, you cut out again on
3 that last part. You said reduce contaminations
4 in?

5 A. In the collected sample.

2020-08-20 Nason Dep. Tr. at 40:4-41:5.

b. **1[a]: a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and**

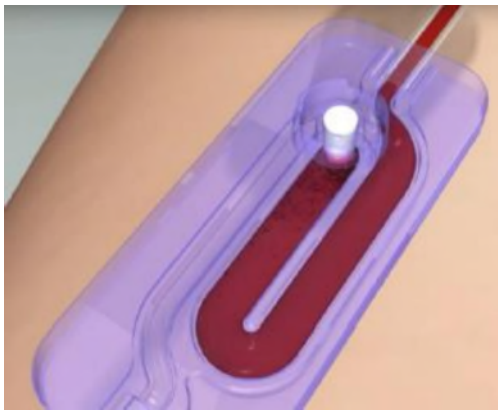
133. The Court construed the term “initial volume” (D.I. 75 at 2):

“initial volume”	“the initial portion of blood removed from the patient and sequestered”
#001 Patent: claims 1, 4, 21-23	
#483 Patent: claims 1, 8, 9, 24	
#139 Patent: claims 1, 13, 19, 23, 27	

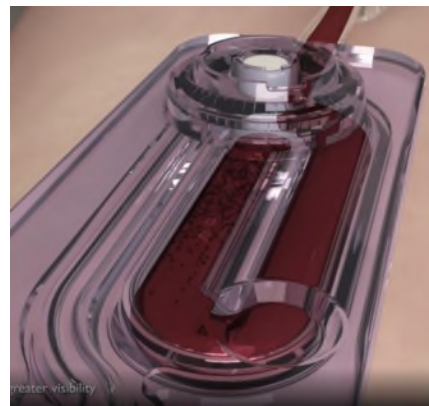
134. Each of the Accused Products includes a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient. *See, e.g.,*

MAG-DEL0000838 (Kurin Video 07/09/2019) (“Kurin is a device designed to contain the initial volume of blood from the venipuncture site so that resident contaminants within the skin are not transferred into the blood culture sample.”); MAG-DEL0826802 (Kurin Video 01/2021) (“The Kurin Lock[®] with Flash Technology sidelines the initial flash of blood from an accessed vein to reduce skin contaminants that enter into the blood culture sample.”)

MAG-DEL0000838 at 0:44:



MAG-DEL0826802 at 0:22:



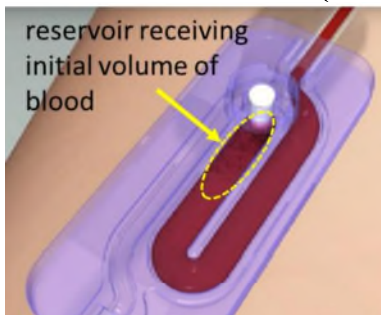
KUR-MAG-DE001632 (IFU_Kurin Blood Culture Collection Set with Kurin Lock[™] Technology) (“The Kurin set is a sterile, single-use blood culture collection set. Kurin includes a winged needle with flexible tubing and an attached blood culture bottle holder intended for venipuncture to obtain blood culture samples. The Kurin Lock blood capture device sequesters the initial draw of blood upon venipuncture.”);

KUR-MAG-DE002283 (IFU_Kurin PIV12 Blood Culture Collection Set with Kurin[®] Lock Technology) (“The Kurin PVV12 series of Kurin sets are sterile, single-use blood culture collection sets that include the Kurin Lock, flexible tubing, an attached blood culture bottle holder, and a male luer intended for direct connection to a freshly placed peripheral IV (PIV) catheter to obtain blood culture samples. The Kurin Lock sequesters the initial draw of blood upon first access to the peripheral catheter.”)

135. The initial volume of blood does not have to be the entire volume of blood contained in the U-shaped diversion chamber. In my opinion, the initial volume of blood is the volume of blood that is actually sequestered in the U-shaped diversion chamber. As shown in the testing videos, a small portion of blood near the junction may (and is expected to) escape the region bounded by the U-shaped diversion chamber. However, the testing videos show that there is a large portion of blood that remains sequestered in the U-shaped diversion chamber. The latter is the initial volume of blood from the patient described by the patents.

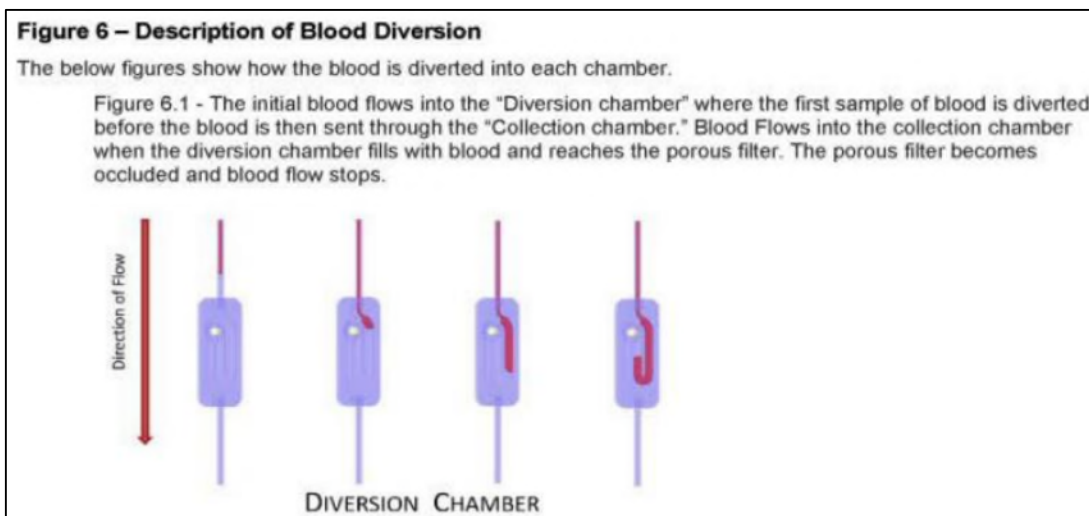
136. The U-shaped diversion chamber includes a reservoir that receives the initial volume of blood from the patient:

MAG-DEL0000838 (Kurin Video 07/09/2019) (annotated):



See also MAG-DEL0826802 (Kurin Video 01/2021)

KUR-MAG-DE000147 (Description of Blood Diversion):



KUR-MAG-DE424575 (How Kurin Works):

6. Blood from the vein flows into the kurin based on patient's pressure! The blood moves into the Kurin and displaces the air located in the kurin. The blood will reach the Kurin plug. When the blood reaches the plug, the plug is activated and the chamber is sealed off. There is also a mechanism in place to prevent the backflow of blood and to lock the contaminated blood into the chamber. In general, If the patient's pressure is normal, blood will flow quicker, then a patient with lower pressure.

KUR-MAG-DE450383

137. Bob Rogers admitted that the initial volume of blood is received in the reservoir of the U-shaped diversion chamber (also known as the side channel) of the Accused Products:

10 Q Well, so the side channel is where the
11 first initial volume of blood goes. Is that fair?
12 MR. HANGARTNER: Objection. Calls for a
13 legal conclusion.
14 THE WITNESS: If the nurse allows, if
15 they insert a needle into the patient and the
16 patient's blood pressure is sufficient, yes, the
17 first amount of blood will go into where there is
18 an air leak, and that's the side channel.

2020-08-18 Rogers Dep. Tr. at 404:10-18.

138. Kevin Nason admitted the same:

17 Q And why is it important to try to
18 fill that side channel before the blood then
19 starts flowing down the sample path into the
20 collection chamber -- collection device?
21 MR. HANGARTNER: Objection.
22 THE WITNESS: Well, the function of
Page 59
1 that is to collect the initial volume of
2 blood in there that potentially has
3 contaminants.

2020-08-20 Nason Dep. Tr. at 58:17-59:3.

- c. **1[b]: a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet,**

139. The Court construed the term “diverter” to be a means-plus-function term (D.I. 75 at 2):

EXHIBIT 9

Videotaped Deposition of
Juan Gabriel Santiago, Ph.D.
April 20, 2021

Magnolia Medical Technologies, Inc.

VS.

Kurin, Inc.

Highly Confidential - Attorneys' Eyes Only



Juan Gabriel Santiago, Ph.D.

Highly Confidential -
Attorneys' Eyes OnlyMagnolia Medical Technologies, Inc. vs.
Kurin, Inc.

<p>Page 1</p> <p>1 IN THE UNITED STATES DISTRICT COURT</p> <p>2 FOR THE DISTRICT OF DELAWARE</p> <p>3 --oOo--</p> <p>4 MAGNOLIA MEDICAL TECHNOLOGIES,</p> <p>5 INC.,</p> <p>6 Plaintiff,</p> <p>7 Case No.</p> <p>8 vs. 2:19-CV-00097-CFC</p> <p>9 KURIN, INC.,</p> <p>10 Defendant.</p> <p>11 _____/</p> <p>12</p> <p>13</p> <p>14 HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY</p> <p>15 VIDEOTAPED REMOTE DEPOSITION OF</p> <p>16 JUAN GABRIEL SANTIAGO, Ph.D.</p> <p>17 _____</p> <p>18 April 20, 2021</p> <p>19</p> <p>20</p> <p>21</p> <p>22 REPORTED BY:</p> <p>23 DELAINE HALL, Sonoma, California</p> <p>24 CSR 10164</p> <p>25 JOB NO. 10080972</p>	<p>Page 3</p> <p>1 A P P E A R A N C E S</p> <p>2 (All participants appearing remotely.)</p> <p>3</p> <p>4 FOR THE PLAINTIFF:</p> <p>5</p> <p>6 DAVIS POLK & WARDWELL, LLP</p> <p>7 1600 El Camino Real</p> <p>8 Menlo Park, California 94025</p> <p>9 BY: MICAH G. BLOCK, Attorney at Law</p> <p>10 (650) 752-2023</p> <p>11 micah.block@davispolk.com</p> <p>12</p> <p>13 FOR THE DEFENDANTS:</p> <p>14</p> <p>15 X-PATENTS, APC</p> <p>16 5670 La Jolla Boulevard</p> <p>17 La Jolla, California 92037</p> <p>18 BY: JONATHAN HANGARTNER, Attorney at Law</p> <p>19 (858) 454-4313</p> <p>20 jon@x-patents.com</p> <p>21</p> <p>22 TURNER BOYD, LLP</p> <p>23 702 Marshall Street, Suite 640</p> <p>24 Redwood City, California 94063</p> <p>25 BY: KAREN I. BOYD, Attorney at Law</p> <p>(650) 521-5930</p> <p>boyd@turnerboyd.com</p> <p>ALSO PRESENT: ANGELA QUACH, Davis Polk</p> <p>GABRIEL ARROWWOOD, Videographer</p> <p>ERIK ANTONSSON</p>
<p>Page 2</p> <p>1 BE IT REMEMBERED that, pursuant to Notice, and</p> <p>2 on Tuesday, April 20, 2021, commencing at 9:03 a.m.,</p> <p>3 thereof, at Stanford, California, before me, DELAINE</p> <p>4 HALL, a Certified Shorthand Reporter, remotely</p> <p>5 appeared</p> <p>6 JUAN GABRIEL SANTIAGO, Ph.D.</p> <p>7 _____</p> <p>8 called as a witness by the Defendant, who having</p> <p>9 been first duly sworn, was examined and testified as</p> <p>10 follows:</p> <p>11 --oOo--</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 4</p> <p>1 I N D E X</p> <p>2 EXAMINATION BY: PAGE</p> <p>3 MR. HANGARTNER: 6</p> <p>4 EXHIBITS MARKED FOR IDENTIFICATION</p> <p>5 NUMBER DESCRIPTION PAGE</p> <p>6 Exhibit 1 Opening Expert Report of 12</p> <p>7 Dr. Juan G. Santiago</p> <p>8 Exhibit 2 Rebuttal Expert Report of 13</p> <p>9 Dr. Juan G. Santiago</p> <p>10 Exhibit 3 Annotated Excerpt from 25</p> <p>11 KUR-MAG-DE001623, first</p> <p>12 page, lower left top view</p> <p>13 Exhibit 4 Page 32 from February 18, 54</p> <p>14 2021 Rebuttal Expert Report</p> <p>15 of Erik Antonsson</p> <p>16 Exhibit 5 Rebuttal Expert Report of 113</p> <p>17 Erik Antonsson, Ph.D., P.E.</p> <p>18 Exhibit 6 Page 36 from February 18, 139</p> <p>19 2021 Rebuttal Expert Report</p> <p>20 of Erik Antonsson</p> <p>21 Exhibit 7 Paragraph 36 from January 15, 186</p> <p>22 2021 Opening Expert Report</p> <p>23 of Juan G. Santiago</p> <p>24</p> <p>25</p>

Page 185

1 the Kurin device that's relevant here?

2 A. No. With respect to the Kurin device, the

3 main body fluid of interest is blood.

4 Q. So I'm going to ask you to go to -- page

5 number here for you.

6 A. Before you ask the next question, is it

7 okay if we take a five-minute break?

8 Q. Absolutely. Why don't we take ten if

9 that's okay. I don't want to push you too late

10 tonight, so if you want it shorter, that's fine.

11 Ten minutes might be nice for everybody. Is that

12 okay with you?

13 A. It's fine with me, yeah.

14 MR. BLOCK: I was going to say let's go

15 off the record and figure it out.

16 VIDEO OPERATOR: Time is 3:25 p.m. Off

17 the record.

18 (Recess taken.)

19 VIDEO OPERATOR: The time is 3:36 p.m. On

20 the record.

21 MR. HANGARTNER: Gabriel, I'm going to ask

22 you to mark tab H as Exhibit 7. It's just an

23 excerpt of paragraph 136, the portion of that

24 paragraph that's on page 102 of Dr. Santiago's

25 January 15, 2021 expert report.

Page 186

1 (Exhibit 7 was marked for identification.)

2 BY MR. HANGARTNER:

3 Q. Dr. Santiago, I'm going to ask you to take

4 a look at that image that's included there. Did you

5 create that dotted yellow oval line on this image?

6 A. Yes.

7 Q. Okay. And -- and you indicate here that

8 that is the reservoir receiving initial volume of

9 blood, correct?

10 A. So this region is the structure that meets

11 the limitation of the reservoir.

12 Q. Okay. And that's in your opinion the

13 structure that meets the limitation of reservoir for

14 all of the asserted claims, correct?

15 A. So you're talking about '001 patent?

16 Q. I'm talking about all of the asserted

17 claims that require a reservoir. I want to make

18 sure it's your opinion that this dotted line

19 reflects what you believe is the reservoir.

20 MR. BLOCK: Object to form.

21 THE WITNESS: So what I said is that that

22 dotted line represents a region that meets the

23 reservoir limitations of, for example, claim 1 of

24 the '001.

25 ///

Page 187

1 BY MR. HANGARTNER:

2 Q. Okay. Is it your opinion that there's

3 some other reservoir in the Kurin device that meets

4 the claim requirements other than this?

5 A. Yes.

6 Q. Okay. Let's go -- why did you choose that

7 dotted yellow line as the reservoir in the Kurin

8 device?

9 A. It's one salient example of a reservoir

10 that's configured to receive an initial volume of

11 bodily fluid withdrawn from the patient.

12 Q. And how did you choose that specific area

13 to encircle with that dotted yellow line?

14 A. Well, it's very consistent with the

15 cartoon picture on which it's drawn.

16 Q. What does that mean?

17 A. So the -- it's drawn on top of a cartoon

18 schematic -- or let's call it a schematic of the

19 Kurin system. And in that system they depict -- or

20 in that drawing they depict contaminants with little

21 black spots. I don't know if you can see those.

22 You can see them more clearly in the original movie.

23 Q. Okay. So this is a still frame from a

24 Kurin promotional video, right?

25 A. So I remember the MAG. The MAG means that

Page 188

1 Magnolia produced the document, but I think the

2 original video was a Kurin video.

3 Q. Okay. And did you choose this still frame

4 to make an image from?

5 A. I did. And I show here one example

6 structure region that meets the limitation of

7 reservoir receiving initial volume.

8 Q. Okay. And why does this region meet those

9 requirements?

10 A. Because it meets the requirements. It's a

11 structure. It's a reservoir. It receives initial

12 volume. Blood in that region and contaminants in

13 that region are sequestered. So I'm good for all

14 those reasons.

15 Q. And it's your understanding that those are

16 the requirements for a reservoir --

17 MR. BLOCK: Object to form. I didn't mean

18 to interrupt you, Jon. Sorry. I thought your

19 question was over. Objection to form.

20 MR. HANGARTNER: No problem.

21 COURT REPORTER: Counsel, I didn't hear

22 the very, very last few words of your question.

23 BY MR. HANGARTNER:

24 Q. As claimed in the asserted patents.

25 A. Those are not the only requirements.

Page 189

1 Q. What other requirements are there?

2 A. Well, for example, claim 1 of the '001,

3 reservoir to receive an initial volume of bodily

4 fluid withdrawn from the patient.

5 Q. Okay. And that's what you said this is on

6 the picture reservoir receiving initial volume of

7 blood, correct?

8 A. That's what is written on the picture.

9 Q. Okay.

10 A. But the claim also recites reservoir

11 again. So it says a diverter having an inlet.

12 First outlet include communication with the

13 reservoir. So there's another requirement that I

14 didn't state previously, and you had asked me if

15 those were the exclusively only definitions of

16 reservoir. If you like, I can go through every

17 mention of reservoir and tell you then what are the

18 limitations for reservoir.

19 Q. That's okay. Thank you, though.

20 This particular yellow circle, I think

21 it's the only opinion you have offered as to the

22 reservoir in your report, correct?

23 A. There are other places in my report where

24 I discuss reservoir, so I'm not sure that's a fair

25 characterization.

Page 190

1 Q. Okay. Well, as you sit here now do you

2 recall defining some other space in the Kurin Lock

3 as the reservoir for purposes of the claims?

4 A. Yes, I recall other uses of reservoir.

5 Q. That's a different question. So -- well,

6 maybe it's not. So any time you identify something

7 as the reservoir in your report you're saying that

8 that satisfies the requirements of the claims with

9 respect to the reservoir?

10 A. What is "that" in that sentence?

11 Q. The reference to reservoir, whatever it's

12 referring to.

13 A. Your question seems either circular or

14 vague. You seem to be asking does reservoir satisfy

15 reservoir? Do you mean to ask if the word

16 "reservoir" as it appears every single place in my

17 report specifically map on to this particular claim

18 in this picture? What is the question?

19 Q. All right. In your report did you express

20 the opinion that some volume other than the one

21 identified in paragraph 136 satisfies the claim

22 requirement for reservoir?

23 A. So just to make it clear, that picture in

24 136 is a rough schematic. It does not mean to

25 delineate what I think is or is not the only

Page 191

1 definition of reservoir or any uniqueness. It

2 doesn't imply any uniqueness. In fact, it's very

3 difficult to delineate a three-dimensional space

4 using a -- an ellipse.

5 Q. Dr. Santiago, did someone tell you you had

6 to present your discussion of reservoir as you have

7 in paragraph 136?

8 A. Are you saying did someone use me as a

9 mouthpiece to speak their words through my mouth?

10 The answer is no.

11 Q. Okay. So -- so you chose to represent the

12 reservoir as it is in paragraph 136, correct?

13 A. I said that that figure and that schematic

14 is a schematic showing a region. And it's one

15 reasonable location or rough approximation of a

16 location that certainly meets the limitation of a

17 reservoir receiving initial volume.

18 Q. Is there any reason you couldn't have been

19 more clear about this?

20 MR. BLOCK: Object to form.

21 THE WITNESS: I've been as clear as I can

22 on this when you just asked me. Would you like me

23 to repeat it?

24 BY MR. HANGARTNER:

25 Q. No, I mean in your expert report. Is

Page 192

1 there somewhere in your expert report where you more

2 clearly define what you believe is the reservoir?

3 If so, please point it to me. This seemed to be the

4 place where you say this is the reservoir receiving

5 the initial volume of blood.

6 A. So this region here, let's call it from

7 the dual valve assembly to about halfway to the

8 180-degree turn. That region is one example region

9 that meets the limitations. So this region is a

10 structure that meets the reservoir requirement. I

11 gave you a second one very clearly earlier in this

12 deposition.

13 Q. No, you didn't. I never heard you say

14 this is the reservoir. So if you're offering new

15 opinions, I'd like to be very clear about that. If

16 you -- we talked about this earlier. You've stated

17 all the opinions you had sitting here this morning

18 in your report. If you have new opinions, please

19 tell me that.

20 MR. BLOCK: Object to form. It's

21 mischaracterizing. It's argumentative.

22 BY MR. HANGARTNER:

23 Q. As you sit here right now do you have some

24 new opinion that was not presented in your report as

25 to what is a reservoir in the Kurin Lock?

Page 193

1 MR. BLOCK: Object to form.

2 THE WITNESS: So earlier we spoke about

3 sequester and sequestering. And that is related to

4 this reservoir and so I mentioned earlier reservoir.

5 If you like, I can say it again.

6 BY MR. HANGARTNER:

7 Q. I would like you to offer any other

8 opinions you have as to what is the reservoir in

9 Kurin Lock in addition to what's shown here in

10 figure 136.

11 A. Okay. So the region in the U tube from

12 the porous plug to the top of the 180-degree turn

13 section, that is a region and a structure that meets

14 the reservoir requirement.

15 Q. That's a different region and structure

16 than what's identified in paragraph 136, correct?

17 MR. BLOCK: Object to form.

18 THE WITNESS: It's a larger region that

19 includes the region depicted in 136.

20 BY MR. HANGARTNER:

21 Q. Okay. So how do I know which one is the

22 reservoir in the Kurin Lock?

23 A. Well, this structure meets the limitation

24 of reservoir of the claims.

25 Q. You're referring to 136?

Page 194

1 A. The 136, that's right. And the larger one

2 I gave you also meets the limitation.

3 Q. How about if I pick another part of that

4 inner leg of the U-shaped side channel, say, from a

5 quarter of the way up the inner leg to

6 three-quarters of the way up the inner leg, is that

7 a reservoir? In your opinion is that a reservoir

8 that satisfies the requirements of claim 1?

9 A. The reservoirs that I've opined on include

10 the region near the porous plug, and you, I think,

11 purposely excluded that region.

12 Q. I did. And I'm asking if the region I

13 identified is in your opinion a reservoir that would

14 satisfy the requirements of claim 1?

15 A. It's not one of the regions I've opined

16 on.

17 Q. Do you have an opinion on that?

18 A. I would say that the reservoir that you

19 described, the structure that you described, meets

20 the limitations of claim 1.

21 Q. Okay. And so you could have just as well

22 offered the opinion that the structure, the area

23 that I described, is the reservoir in the Kurin Lock

24 as what you've done here.

25 A. I could have. I don't understand. I

Page 195

1 either did or did not, and I gave my opinion now

2 very clearly. So I don't understand "you could

3 have." I don't understand that.

4 Q. When you go to trial what opinion will you

5 offer as to the boundaries of the reservoir in the

6 Kurin Lock?

7 A. So one opinion is depicted here in this

8 136.

9 Q. Okay.

10 A. Let's call it from the porous plug region

11 until, say, two-thirds of the way up to the

12 180-degree turn. That is definitely a structure

13 that meets the limitations. A second structure --

14 so the Kurin Lock meets these limitations in several

15 ways. Another way that it meets the limitations is

16 defining the reservoir or the structure -- or the

17 structure starting from the porous plug to the top

18 of the 180-degree turn.

19 Q. Any others?

20 A. I would say from the porous plug to

21 halfway to the 180-degree turn.

22 Q. So is it fair to say it's your opinion

23 that if we draw the boundaries starting at the

24 porous plug and extending any of the distance down

25 to the 180-degree turn, we can pick any spot in

Page 196

1 there and say that's the reservoir?

2 A. I'm saying that the Kurin Lock meets the

3 limitation in at least several ways, and these

4 reservoirs meet the limitation.

5 Q. That's not my question. Could I start at

6 the porous plug and go into the U-shaped channel

7 beyond the porous plug any distance all the way to

8 the 180-degree turn, just pick a spot, draw a line,

9 and call that the reservoir?

10 MR. BLOCK: Object to form.

11 THE WITNESS: I think it's most useful to

12 identify specific structures. And for those reasons

13 I said either two-thirds of the way or one-half of

14 the way since these are easy fractions to identify.

15 Also, from the porous plug to the top of the

16 180-degree. Those three examples I gave you are

17 structures in the Kurin Lock which meet the

18 limitation of reservoir.

19 BY MR. HANGARTNER:

20 Q. How about if I extended it from the porous

21 plug to your line at the apex of the 180-degree

22 turn, and then I went four more millimeters around

23 the corner and drew a line there? Would that --

24 would that be the reservoir in the Kurin Lock?

25 A. So four more millimeters in which

Page 197

1 direction?

2 Q. Around toward the outer leg of the

3 U-shaped channel.

4 A. So I didn't offer that opinion.

5 Q. And I'm asking you would that be a

6 reservoir in the -- in the Kurin Lock?

7 A. So I'm -- I don't have an opinion about

8 that today or in my report.

9 Q. Do you have an opinion about that today?

10 A. No.

11 Q. How about I took it from the porous plug

12 and went halfway around so that I was halfway up the

13 outer leg of the U-shaped channel and I drew my line

14 there? Would that be a reservoir?

15 A. I don't have an opinion about that today.

16 Q. And you haven't offered one in your

17 report, have you?

18 A. No.

19 Q. Is there -- is there any other reservoir

20 in the Kurin Lock other than the ones you've

21 already -- you just talked about?

22 A. I've talked about three possible ones at

23 least. Are you saying are there other regions?

24 Like, for example, the sample channel is not a

25 reservoir. Is not the reservoir.

Page 198

1 Q. Okay. I was asking if there's any other

2 region. So in your opinion once it crosses a

3 vertical line at the apex of the turn from the inner

4 leg of the U channel to the outer leg, once we cross

5 that line, in your opinion it's no longer the

6 reservoir?

7 MR. BLOCK: Object to form.

8 THE WITNESS: No, that's not what I said.

9 BY MR. HANGARTNER:

10 Q. You have no opinion as to whether it's the

11 reservoir once you cross that line?

12 A. That's right. It could be and may or may

13 not be a reservoir.

14 Q. And how would I determine whether it's a

15 reservoir or not?

16 A. Well, if -- what's the important question

17 is does it meet the limitations.

18 Q. Okay. And what changes as you come around

19 that corner that would alter whether it meets the

20 limitations?

21 A. Nothing might change immediately as you go

22 around the corner.

23 Q. Okay. Or as you go further around the

24 corner, what changes?

25 A. The location of where you are. What I'm

Page 199

1 pointing to is a very definite structure with

2 definite bounds which meets the limitation, and it's

3 a structure in the Kurin device.

4 Q. And that definite bound is the dotted line

5 that you have shown there?

6 A. No. I was talking about the largest

7 reservoir that I described to you.

8 Q. The new opinion that you just offered

9 today?

10 A. Actually, I think there's good support in

11 my report for the -- I wouldn't call it a new

12 opinion. There's good support in my report for that

13 180-degree line.

14 Q. Even though here you have a picture -- do

15 you have another picture that shows a mark at the

16 180-degree line saying that's the reservoir?

17 A. I have other very good language, very

18 clear.

19 Q. I want to point you to paragraph 50 of

20 your report. It's on page 25. And this is talking

21 about the background on the Kurin device. And it

22 refers to figure 2, which is a photograph that I

23 think you took below, correct?

24 A. Yes, I took that photograph.

25 Q. Okay. Now, in this you describe the

Page 200

1 device as including an inlet and a Y junction with

2 two outlets. And you indicate that at the Y

3 junction you say that is where the single inlet

4 channel bifurcates into two daughter channels.

5 Do you see that at about a third -- you

6 know, few sentences down in paragraph 50?

7 A. The inlet channel leads to a geometry that

8 could be roughly described as a Y junction where the

9 single inlet channel bifurcates into two daughter

10 channels.

11 Q. Okay. So then -- I'm going to skip the

12 next sentence because it's about the capillary burst

13 tube. You say the Y junction is not easily visible

14 in the image of figure 2, but can be described as

15 follows. And you have a detailed description of the

16 Y -- of the geometry, correct?

17 A. I have a description of the geometry with

18 some detail, but it's hard to put three-dimensional

19 geometries into either two-dimensional images or

20 words.

21 Q. But this is the best you could come up

22 with, right?

23 MR. BLOCK: Object to form.

24 THE WITNESS: I don't know if it's the

25 best that I've ever done, but it's my description I

Page 201

1 put in my report.
 2 BY MR. HANGARTNER:
 3 Q. You wrote it, right?
 4 A. I wrote it, yes.
 5 Q. And at the time you were trying to do a
 6 good job, right? You weren't trying to make this
 7 confusing, right?
 8 A. No.
 9 Q. Your goal was clarity, correct?
 10 A. Yeah, clarity and being accurate. I
 11 wanted to be accurate.
 12 Q. Okay. So the next sentence in the
 13 description goes like this: The three-dimensional
 14 structure of this junction is such that the first of
 15 these daughter channels rapidly transition into a
 16 channel with a significantly larger cross-sectional
 17 area than either the inlet channel or the second
 18 daughter channel. This large cross-sectional area
 19 first daughter channel (also known as a U-shaped
 20 diversion chamber) extends throughout most of the
 21 length of the device, and then bends at a U-turn as
 22 shown in figure 2.
 23 So this description is talking very
 24 specifically about the U-shaped side channel from
 25 the point where it diverges from the inlet, correct?

Page 202

1 MR. BLOCK: Object to form.
 2 THE WITNESS: That part about the from the
 3 point is something you have imported into the text.
 4 BY MR. HANGARTNER:
 5 Q. No. It's actually what it says right
 6 there. It says this -- it's referring to this
 7 daughter channel as a daughter channel from the
 8 inlet. It starts at the inlet itself and defines
 9 this as a daughter channel of the inlet, correct?
 10 MR. BLOCK: Object to form.
 11 THE WITNESS: So what I say is that the
 12 first of the two daughter channels rapidly
 13 transitions into a channel with significantly larger
 14 cross-sectional area. You seem to have forgotten
 15 that part about rapidly transitioning into the
 16 channel.
 17 BY MR. HANGARTNER:
 18 Q. That occurs immediately in the Y junction
 19 area, doesn't it?
 20 A. What do you call immediately?
 21 Q. Does the rapid transition you described
 22 here occur in the area of Y junction?
 23 A. It's near -- it's near the junction --
 24 near the Y junction, yes. In the vicinity of the Y
 25 junction.

Page 203

1 Q. Okay, okay. So you're telling me that the
 2 transition in the cross-section doesn't happen until
 3 you are past what you call the Y junction?
 4 MR. BLOCK: Object to form.
 5 THE WITNESS: I'm saying that my analyses
 6 and opinions regarding infringement don't depend on
 7 the exact delineation between the inlet channel and
 8 the exact transition to the U-shaped chamber.
 9 BY MR. HANGARTNER:
 10 Q. No. You're answering not the question I'm
 11 asking in any way. And I'd appreciate it if you'd
 12 answer my question.
 13 MR. BLOCK: Object to form.
 14 BY MR. HANGARTNER:
 15 Q. Does the -- you have previously indicated
 16 that certain things, such as mixing, occur within
 17 and slightly without the Y-shaped junction area,
 18 correct?
 19 A. That's not exactly how I said it, but I
 20 said that the mixing regions are near the Y
 21 junction.
 22 Q. Okay. The Y junction area, does it extend
 23 to the point where the daughter, the first daughter,
 24 channel expands in cross-section?
 25 A. There is some transition between the

Page 204

1 immediate bifurcation and the expanded
 2 cross-sectional area. In this text I don't
 3 necessarily attribute that to the Y junction or the
 4 daughter channel. I just describe it as a
 5 transitional area between the two.
 6 Q. Okay. So the structure you are talking
 7 about in this paragraph is the U-shaped side
 8 channel, correct?
 9 A. I'm speaking of more than that.
 10 Q. All right. Look, the large
 11 cross-sectional area. So let's start at that
 12 boundary. You agree that this -- you called it the
 13 first daughter channel, so I'm going to call it
 14 that. The first daughter channel from the inlet
 15 after bifurcation has -- it changes to a larger
 16 cross-sectional area. That is what this says,
 17 correct?
 18 A. No.
 19 Q. Okay. Tell me what this says. Actually,
 20 no, don't do that. You're going to -- you're going
 21 to change it. Here's what it says. There's a large
 22 cross-sectional area. That's referring to the area
 23 that begins where the cross-section becomes bigger,
 24 right?
 25 A. The increase of the cross-sectional area

<p style="text-align: right;">Page 205</p> <p>1 refers to the larger cross-sectional of the larger 2 channel, yes. 3 Q. And that begins at or very close to the Y 4 junction, correct? 5 A. I speak of a transition between them. 6 Q. Yes. And so you're saying that the Y 7 junction ends, and there's a transition to a larger 8 cross-section daughter channel, correct? 9 A. Not necessarily. 10 Q. Okay. Explain to me the relationship 11 between the Y junction area that you talk about here 12 and the larger cross-section area where this becomes 13 what we've calling the U-shaped side channel. What 14 is the relationship between those two? 15 A. Well, there's a region which is a Y 16 junction which includes a single inlet bifurcating 17 into two daughter channels. One of those two 18 daughter channels -- or the flow traveling through 19 the first of those two daughter channels would 20 experience a transition region where the 21 cross-sectional area increases and eventually would 22 reach the U-shaped channel. 23 Q. Okay. And is that transition region 24 within or without the Y shaped junction, the Y 25 junction?</p>	<p style="text-align: right;">Page 207</p> <p>1 larger cross-section, are we in what you refer to 2 here as the U-shaped diversion chamber? 3 A. So at some distance from the Y junction 4 you are in there. And, if you like, we can go to a 5 picture and I can tell you a region where I'm sure 6 you're in the U junction. 7 Q. Okay, that's great. Let's try that. 8 Let's look at -- if you have a picture that you 9 think would be helpful, please point it out to me. 10 A. Yeah. It is in my report on page 106. 11 Q. Okay. And this is again the drawing we 12 were referring to earlier from the Kurin engineering 13 drawings. Which one of these drawings would you 14 like to refer to? 15 A. The one on the bottom right that's labeled 16 top housing Kurin Lock. 17 Q. Okay. So the very bottom right showing 18 on -- there's two images, and you are referring to 19 the one on the left, correct? 20 A. No. Actually I'm talking about the one on 21 the right, the isometric view. 22 Q. The blue or purple. 23 A. The blue. That's right. 24 Q. Okay. Go ahead. 25 A. So I think I've been very reasonable in</p>
<p style="text-align: right;">Page 206</p> <p>1 A. My analysis didn't need a precise 2 delineation of those two three-dimensional shapes. 3 Q. The idea of this being a Y junction is 4 yours, correct? You are the one who uses this term 5 and is using it throughout your report, correct? 6 A. Yeah, and it's a very reasonable term. 7 Q. Okay. I'm asking you where does the Y 8 junction include the area of transition to the 9 larger cross-section? 10 A. I'm saying that level of precision is 11 difficult because of the three-dimensional nature 12 and is not needed -- was not needed for my opinion. 13 Q. So as you sit here now do you have any 14 opinion as to where the Y junction ends with respect 15 to that transition? 16 A. Other than they are near, and I described 17 them as well as I can, but these are 18 three-dimensional regions that are difficult to 19 describe. It's three-dimensional space and you 20 would like me to -- what would you like? You would 21 like a three-dimensional surface that divides the 22 several components? Is that what you would like? 23 Q. You refer to this large cross-sectional 24 area first daughter channel. Once the transition 25 eventually, as you said, reached the area of the</p>	<p style="text-align: right;">Page 208</p> <p>1 describing this as a highly three-dimensional 2 region. Keep in mind that the bounded region where 3 there is fluid is bounded by the gray piece on top, 4 and the blue piece on the bottom, and each of those 5 two has three-dimensional surfaces. 6 Three-dimensional curved surfaces. So -- and you'll 7 also, I think, agree that the U tube chamber has a 8 larger cross-sectional area than, say, the inlet. 9 Inlet is a tube that attaches to the device. 10 Q. Right, okay. 11 A. So I would say you're well into the U tube 12 chamber, for example, as you -- as the channel 13 straightens out into the straight portion of the U 14 tube, now you're well -- I'm certain there that are 15 you are in the U tube chamber now. 16 Q. But, in fact, the cross-section opens -- 17 becomes larger earlier than that, doesn't it? 18 A. Slightly earlier. But if you look, that 19 ridge, like what you pointed to as point A this 20 morning, is not a point. It's actually a whole 21 series of edges and three-dimensional curved, convex 22 surfaces. So they extend into it. If you look at 23 the top like the gray, you see how there's a whole 24 sort of transition even as you go into the turn. 25 Q. Right, as you start into the turn. But</p>

Page 209

1 that transition is complete. If you look at the
2 engineering drawing of the four pictures here on the
3 top left, you can see lines indicating that
4 transition region directly. If you follow the point
5 of point A down and to the left, there are lines
6 showing that transition region, correct?
7 MR. BLOCK: Object to form.
8 THE WITNESS: That's a transition between
9 relatively small and relatively large
10 cross-sectional areas. It's not necessarily where
11 you're in the U. It depends on whether you lump the
12 turn into the U or not.
13 BY MR. HANGARTNER:
14 Q. Okay. So let's go back to paragraph 50,
15 because I think you have explained exactly what you
16 mean quite well here. And you said that the large
17 cross-sectional area first daughter channel extends
18 throughout most of the length of the device, and
19 bends at a U turn as shown in figure 2.
20 Now, I'm going to skip over the next
21 sentence. But then I'm going to read the last which
22 says: "The volume of this first daughter channel
23 downstream of the Y junction and up to the valve
24 assembly region acts as a reservoir or so-called
25 flash chamber where an initial of volume of

Page 210

1 contaminated blood is to be sequestered."
2 Is that an accurate statement?
3 A. You read that correctly.
4 Q. Is that an accurate statement of your
5 opinions?
6 A. So I would say the downstream portion of
7 that volume is the reservoir.
8 Q. But the statement in your report at
9 paragraph 50 is correct?
10 MR. BLOCK: Object to form.
11 THE WITNESS: I'm not sure that's true,
12 but I'm happy to explain my opinion.
13 BY MR. HANGARTNER:
14 Q. No, no. I have a very simple question.
15 Is this description of the reservoir accurate?
16 A. So this specifies a volume that is
17 downstream of the Y junction, and the volumes I've
18 been describing are all downstream of the Y
19 junction.
20 Q. So you believe that paragraph 50
21 accurately states your opinions in this case?
22 A. Well, the volumes that I've been
23 describing are downstream. Even that 180-degree
24 turn way at the top is downstream of the junction.
25 Q. When you refer -- okay. I have a really

Page 211

1 simple question. It's yes or no. Is this an
2 accurate statement?
3 MR. BLOCK: Object to form.
4 THE WITNESS: I can see how you might
5 think it's somewhat vague, but I think I'm
6 referring -- well, I am referring to the region
7 downstream. And that's a region -- I didn't mean to
8 write that it's immediately downstream. Maybe
9 that's the confusion.
10 BY MR. HANGARTNER:
11 Q. What's the plain and ordinary -- ordinary
12 meaning of withdraw?
13 MR. BLOCK: Object to form.
14 THE WITNESS: All right. So I want to
15 make sure -- you're changing gears here completely,
16 so let me catch up with you. I'm opening the claim.
17 I think you are talking about with respect to claim
18 '001.
19 BY MR. HANGARTNER:
20 Q. Withdraw is included in claim '001. I'm
21 referring to the plain and ordinary meaning of the
22 claim term withdraw.
23 A. So you're asking me the plain, ordinary
24 meaning of the withdraw in the absence of these
25 patents as if they didn't exist?

Page 212

1 Q. Yeah. I'm just asking for the plain and
2 ordinary meaning of the term "withdraw." It is a
3 term used in the claims. My question to you is what
4 is the plain and ordinary meaning of the term
5 "withdraw"?
6 MR. BLOCK: Object to form.
7 THE WITNESS: And you want me for a second
8 to pretend that these patents don't exist?
9 BY MR. HANGARTNER:
10 Q. No. Patents are understood in accordance
11 with their plain and ordinary meaning, correct?
12 MR. BLOCK: Object to form.
13 BY MR. HANGARTNER:
14 Q. This is -- this is not a trick question.
15 It's not a complicated question. What is withdraw?
16 MR. BLOCK: Same objection.
17 THE WITNESS: So I read the claims and the
18 claim terms in the way that a person of ordinary
19 scale in the art would read them in light of the
20 specification. So I think you're -- now you're
21 asking me to forget these patents; is that right?
22 BY MR. HANGARTNER:
23 Q. No, I'm not.
24 A. Okay.
25 Q. I'm not asking you to forget the patent.

Page 253

1 question.

2 THE WITNESS: So as I understand in order

3 to be analogous art, it should be --

4 BY MR. HANGARTNER:

5 Q. I'm sorry. I'm sorry. I'm sorry to

6 interrupt you. Can you tell me what you're looking

7 at right now and where you've gone to in your report

8 to answer this question?

9 A. So I've looked at a few things. Right

10 now, if you like, I can -- let's see, first

11 paragraph 28 of my validity report.

12 Q. Okay. Thank you. I'm sorry to interrupt

13 you.

14 MR. BLOCK: There's no question pending,

15 Jon, if you want to clean up the record.

16 MR. HANGARTNER: Yeah, sure.

17 Can you read back the last substantive

18 question that I asked?

19 (Record read as follows: Q. What

20 criteria would you use to determine

21 whether a particular medical device is

22 analogous art or not? And refer to your

23 report. Go at it. Spend an hour.

24 Whatever you want to do. Just please

25 actually answer that question for me.)

Page 254

1 MR. BLOCK: Object to form.

2 THE WITNESS: Should I go ahead and

3 answer?

4 BY MR. HANGARTNER:

5 Q. Yeah, please.

6 MR. BLOCK: Yes, you may answer.

7 THE WITNESS: So analogous art is

8 either -- refers to a publication, a prior art, that

9 is either in the same field of endeavor, or at least

10 reasonably pertinent to the problem that the

11 inventor was trying to solve. And further, as you

12 can read in my report, I understand that a reference

13 is only reasonably pertinent when it's logical, when

14 it logically would have commended itself to an

15 inventor's attention in considering the problem.

16 BY MR. HANGARTNER:

17 Q. Did you write paragraph 28, Dr. Santiago?

18 A. I would say that particular paragraph was

19 a collaborative effort.

20 Q. With the lawyers, right?

21 A. That's right.

22 Q. And you just read back to me the words in

23 paragraph 28 of your report in answer to my

24 question?

25 A. No, not exactly. I changed some of the

Page 255

1 words, and I said it in my own words just now.

2 Q. All right. We've done enough. Excellent.

3 Let's go off the record. Great job stalling out the

4 last hour. Somewhat admirable.

5 VIDEO OPERATOR: The time is 5:43. Off

6 the record.

7 (Signature having not been waived,

8 the deposition of Juan Santiago was

9 concluded at 5:44 p.m.)

Page 256

1 CERTIFICATE OF SHORTHAND REPORTER

2

3 I, Delaine Hall, Certified Shorthand

4 Reporter, the officer before whom the

5 foregoing proceedings were taken, do hereby

6 certify that the foregoing transcript is a true

7 and correct record of the proceedings; that said

8 proceedings were taken by me stenographically and

9 thereafter reduced to typewriting under my

10 supervision; and that I am neither counsel for,

11 related to, nor employed by any of the parties to

12 this case and have no interest, financial or

13 otherwise, in its outcome.

14 Further, that if the foregoing pertains to

15 the original transcript of a deposition in a federal

16 case, before completion of the proceedings, review of

17 the transcript [X] was [] was not requested.

18 IN WITNESS WHEREOF, I have hereunto set

19 my hand and affixed my signature this 4th day of

20 May 2021.

21

22

23

24 _____

25 DELAINE HALL, CSR 10164

EXHIBIT 10

FILED UNDER SEAL

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 17

**MAGNOLIA’S OPPOSITION TO KURIN’S MOTION *IN LIMINE* NO. 1:
TO PRECLUDE EVIDENCE OR ARGUMENT RELYING ON
DR. SANTIAGO’S NEW DEFINITION OF RESERVOIR**

Kurin’s Motion *in Limine* No. 1 is an untimely challenge to Dr. Santiago’s “reservoir” opinion. The Court already rejected Kurin’s similar request at the *Daubert* stage. *See* Ex. 17.A (Summary Judgment Hr’g Tr.) at 38:13–40:8, Feb. 10, 2022. The opinion is not only reliable but also appropriately disclosed, and Kurin has been aware of it for more than a year. The motion should be denied.

First, the motion is untimely. Kurin concedes that—at the latest—Magnolia disclosed the pertinent opinion more than a year ago in Dr. Santiago’s January 15, 2021 expert report and April 20, 2021 deposition. Mot. at 2. But Kurin never moved to strike, choosing instead to raise only an unsuccessful *Daubert* challenge. *See* D.I. 289. When the Court observed at the February 10, 2022 *Daubert* hearing that the *Daubert* motion was not “the vehicle” to assert purported surprise or prejudice, Ex. 17.A at 41:14–16, Kurin waited a further three months before bringing this motion. Kurin cannot now complain of purported prejudice that it made no effort to cure. *See Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 905 (3d Cir. 1977) (reversing exclusion because “assertion of surprise and prejudice had to be viewed in the context of [movant’s] own failure to take any steps to clarify the facts”) (abrogated on other grounds).

Moreover, the *Pennypack* factors weigh against the “extreme sanction” of exclusion. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791–92 (3d Cir. 1994).

(1) Prejudice or surprise. As Magnolia has previously explained, there is

no prejudice or surprise because Magnolia provided notice of its contentions and appropriately developed them in expert discovery. D.I. 337 at 3–4; *see, e.g., TQ Delta v. ADTRAN*, C.A. No. 14-954-RGA, 2021 WL 3633637, at *2 (D. Del. Aug. 17, 2021) (declining to exclude expert disclosures that “expand on” infringement theories of contentions); *Vectura Ltd. v. GlaxoSmithKline, LLC*, C.A. No. 16-638-RGA, 2019 WL 1436296, at *2 (D. Del. Apr. 1, 2019). Moreover, Kurin had every opportunity to test and respond to the opinions—and did so, in its expert’s rebuttal report and in its deposition of Dr. Santiago. *See* Ex. 17.B (Antonsson Rbtl. Rpt.) ¶¶ 87–88, 148, 411; Mot. Ex. 9 at 185:21–198:13. This negates any purported prejudice, as Kurin’s case law acknowledges. *TQ Delta, LLC v. ADTRAN, Inc.*, C.A. No. 14-954-RGA, 2019 WL 4346530, at *3–4 (D. Del. Sept. 12, 2019) (no prejudice where party “had the opportunity to respond to [the challenged] theories and to depose [the expert] on his report”); *see Evolved Wireless, LLC v. Apple Inc.*, C.A. 15-542-JFB-SRE, 2019 WL 1100471, at *2–3 (D. Del. Mar. 7, 2019).

Kurin asserts that it might have conducted different or additional tests of its own device. Mot. at 2–3. But Kurin’s expert’s tests are dated weeks *after* Dr. Santiago’s January 15, 2021 expert report. *See* Mot. Ex. 7 at 301 (showing test dates Jan. 28 to Feb. 8, 2021). Moreover, those tests (in the “Background of the Accused Infringing Kurin Device” section) simply show the operation of the Kurin

Lock. *See* Mot. Ex. 7 at ¶¶ 89–119.¹ Nothing about them depends on Dr.

Santiago’s “reservoir” opinion.²

(2) The possibility of curing the prejudice. As noted above, Kurin had Dr. Santiago’s opinion in his January 15, 2021 expert report and April 2021 deposition. Had there been unfair prejudice, there was ample time to cure if Kurin acted timely. *See Pennypack*, 559 F.2d at 905.

(3) The potential disruption of trial. Kurin does not and cannot assert that permitting Dr. Santiago’s “reservoir” opinion will disrupt the trial. Mot. at 2–3.

(4) Bad faith or willfulness in failing to disclose the evidence. Neither bad faith nor willfulness is present here. Magnolia timely disclosed its contentions and expert opinions according to the Court’s schedule. *See supra*.

(5) The importance of the information withheld. Nothing was withheld. However, although Dr. Santiago’s “reservoir” opinion is not dispositive, it is important. If Kurin believed otherwise, it would not be moving to exclude.

¹ Kurin cites other tests conducted in fact discovery. Mot. at 1. But Dr. Antonsson disclaimed reliance on them. Ex. 17.C (Antonsson Dep. Tr.) at 43:22–47:2.

² Kurin’s cases do not apply. Whereas the “reservoir” theory here was disclosed in Magnolia’s contentions and refined in Dr. Santiago’s report and deposition, Kurin’s cases involved efforts to introduce entirely new DOE allegations for the first time via expert report, *Viatech Techs., Inc. v. Microsoft Corp.*, C.A. No. 17-570-RGA, 2021 WL 663057, at *2 (D. Del. Feb. 19, 2021); *ASUS Comp. Int’l v. Round Rock Rsch., LLC*, C.A. No. 12-2099-JST-NC, 2014 WL 1463609, at *2–3 (N.D. Cal. Apr. 11, 2014), or to introduce new expert theories in the pretrial order. *Pharmacyclics LLC v. Cipla Ltd.*, C.A. No. 18-192-CFC-CJB, 2020 WL 6581643, at *2 & n.2 (D. Del. Nov. 10, 2020).

EXHIBIT 17.A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL)
TECHNOLOGIES, INC.,)
Plaintiff,) C.A. No. 19-97 (CFC) (CJB)
v.)
KURIN, INC.,)
Defendant.)

Thursday, February 10, 2022
9:00 a.m.
Motion Hearing

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE COLM F. CONNOLLY
United States District Court Judge

APPEARANCES:

RICHARDS, LAYTON & FINGER
BY: KELLY E. FARNAN, ESQ.

--and--

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
BY: NICHOLAS GROOMBRIDGE, ESQ.
BY: CATHERINE NYARADY, ESQ.
BY: JOSHUA REICH, ESQ.

Counsel for the Plaintiff

1 offering an opinion which is not using functional language.
2 And if they are going to limit themselves to that, then
3 should I not just say, let it go?

4 **MR. GROOMBRIDGE:** I -- no, Your Honor, for several
5 reasons.

6 First of all, on the structure, it -- I'm holding
7 up a plastic bottle. If we take the top off, it's open, but
8 we all still agree it's a bottle. If I say the bottom third
9 or maybe the bottom half of it is what I'm talking about, is
10 that a bottle? Most people would say no.

11 **THE COURT:** Yeah, but now we are getting into --
12 let the jury decide that.

13 **MR. GROOMBRIDGE:** The -- and here we have the
14 testimony that you didn't see in Magnolia's argument where
15 he's being asked:

16 "When it crosses the vertical line, that's the
17 180-degree mark, right? Is that, in your opinion, is it a
18 reservoir?"

19 And some back and forth here.

20 "You have no opinion?"

21 "That's right. It could be. It may or may not be
22 a reservoir."

23 And that's what's going on here. It's a totally
24 moving target, Your Honor, and that this is the problem that
25 we've got. No one can tell under their theory they do or

1 don't.

2 **THE COURT:** So is your contention for
3 indefiniteness?

4 **MR. GROOMBRIDGE:** There would have been had this
5 been raised in a timely fashion.

6 **THE COURT:** Well, that's where you get into the --
7 that's not a *Daubert* motion, but that's a *Pennypack*. Let's
8 just deal with *the Daubert* -- this is a *Daubert* motion,
9 right?

10 **MR. GROOMBRIDGE:** This is a *Daubert* motion.

11 **THE COURT:** So let's deal with the *Daubert* part of
12 it, and -- I mean, you know, again, boy, aren't you going to
13 have fun with their expert on the stand here? I mean, my
14 goodness. It is a jury trial, right?

15 **MR. GROOMBRIDGE:** It is a jury trial, Your Honor.

16 **THE COURT:** You'd have fun with me in front of
17 it --

18 **MR. GROOMBRIDGE:** I -- I think -- I think I would,
19 Your Honor.

20 **THE COURT:** -- the guy is a moving target.

21 Which I go back to in a way, I sometimes wonder why
22 we are bringing these motions. But, you know, just limit
23 yourselves to *Daubert*, right? They've got an opinion. They
24 say they are going to limit themselves to lines 10 through
25 17, which is structure.

1 All right. It sounds like maybe I should just deny
2 the motion. That's what they get to do.

3 **MR. GROOMBRIDGE:** Well, Your Honor, I think what we
4 would want to be clear on the record is we think that it
5 implicates a claim construction dispute, late-breaking claim
6 construction dispute, about "reservoir."

7 I understand Your Honor may not agree with us, but
8 I just want to be clear.

9 **THE COURT:** Well, how would you define "reservoir"?

10 **MR. GROOMBRIDGE:** I would say that it's a -- in the
11 context of these patents when looking -- what the word
12 "reservoir" means in these patents, it is some form of
13 enclosed space that's bounded -- its boundaries can't be
14 defined. And it can be -- it has an opening for sure,
15 because things have to get into it, but that's what it is.
16 It's boundaries other than the opening, a physical
17 structure. And that --

18 **THE COURT:** Right. Well, I don't think that --
19 just for the record, you know, I don't think that that
20 definition you proffered implicates 02 micron because you
21 are talking about an opening. Anytime you have an opening,
22 you do not have a physical barrier.

23 Both sides have defined "structure" with having a
24 part, a physical barrier, which is the housing, and -- but
25 both sides right now, including what you've just proffered,

1 posit a definition of reservoir which would have at least
2 some portion of the reservoir being undefined by physical
3 barrier.

4 So for that reason, it is not 02 micron, and I'm
5 going to deny the *Daubert* motion because I think they have
6 actually shown that they have structural definition, which
7 they stipulated they are going to limit themselves to. And
8 if at any point they try to define or justify the opinion by
9 resort to functionality, I will entertain any motion in
10 limine to strike it, do whatever we have to.

11 I can explain to the jury how they said this is a
12 "means plus function" term and it was not defined in terms
13 of functionality. They'll pay a price if they did that.

14 Now, as far as the issue of the fairness of it, and
15 was this raised late, it just doesn't seem this is the
16 vehicle by which it should be presented to me.

17 **MR. GROOMBRIDGE:** I understand, Your Honor, and
18 duly noted.

19 And I was smiling because when Your Honor referred
20 to opening, it made me think if you give a lawyer an
21 opening, they will take it.

22 **THE COURT:** Yes.

23 All right. So anything else you want to say,
24 though, in terms of *the Daubert*-based motion?

25 **MR. GROOMBRIDGE:** No, Your Honor. We understand

EXHIBIT 17.B

FILED UNDER SEAL

EXHIBIT 17.C

FILED UNDER SEAL

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

)
)
)
) C.A. No. 1:19-cv-00097-CFC
) (CJB)
)



**KURIN’S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 1
TO PRECLUDE EVIDENCE OR ARGUMENT RELYING ON
DR. SANTIAGO’S NEW DEFINITION OF RESERVOIR**

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &

GARRISON LLP

1285 Avenue of the Americas

New York, NY 10019-6064

(212) 373-3000

Attorneys for Defendant Kurin, Inc.

June 3, 2022

Magnolia cites to nothing contradicting this Court’s precedent disallowing presentation of a theory not in its infringement contentions. Magnolia notably offers no support for its footnoted insinuation that the Santiago theory was disclosed in its contentions and only “refined” in his report. Nor do its cases say that a “refinement” that seeks to salvage a failed theory is exempt from the good-cause requirement under the scheduling order. *Magnolia* has the burden to show good cause in adding a new theory. It does not even attempt to do so. It is thus only Magnolia’s attempt to assert the theory at trial that is untimely, not Kurin’s motion. *Pharmacyclics LLC v. Cipla Ltd.*, 2020 WL 6581643, at *3 (D. Del. Nov. 10, 2020). In any case, Kurin brought this motion at the earliest opportunity—promptly after denial of its *Daubert* motion that previewed, and would have obviated, this motion. D.I. 289 at 3–6.

On prejudice, Dr. Antonsson’s tests underlying his noninfringement opinions, *see, e.g.*, Ex. 11 ¶ 155, like the prior tests Kurin relies on for noninfringement, *see* Ex. 6, were ***designed*** prior to Dr. Santiago’s report, to rebut Magnolia’s contention “reservoir” theory. Dr. Antonsson and Kurin had no time to redesign and redo tests to rebut Santiago’s new theory. As Kurin’s cases make clear, timely disclosure would have allowed Kurin and Dr. Antonsson ***during fact discovery*** to design tests targeted to determine whether mixing occurred specifically in Dr. Santiago’s narrower “reservoir” as opposed to the contentions’ broader “reservoir”. And, as Kurin explained, such prejudice cannot be cured before trial. MIL No. 1 at 2–3.

RICHARDS, LAYTON & FINGER,
P.A.

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
kraman@paulweiss.com
jreich@paulweiss.com
abarel@paulweiss.com

/s/ Kelly E. Farnan
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

June 3, 2022

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**DECLARATION OF ARIELLA BAREL IN SUPPORT OF KURIN, INC.'S
REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 1 TO
PRECLUDE EVIDENCE OR ARGUMENT RELYING ON
DR. SANTIAGO'S NEW DEFINITION OF RESERVOIR**

I, Ariella Barel, declare as follows:

I am a member in good standing of the bar of the State of New York, First Department and am associated with Paul, Weiss, Rifkind, Wharton & Garrison LLP, counsel for Defendant Kurin, Inc. (“Kurin”) in this action. I have been admitted *pro hac vice* for this matter. I respectfully submit this Declaration in support of Kurin’s reply in support of its Motion *in Limine*, which is filed herewith.

1. Attached hereto as **Exhibit 11** is a true and correct copy of an excerpt of the Rebuttal Expert Report of Erik K. Antonsson, dated February 18, 2021.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on June 3, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 11

FILED UNDER SEAL

EXHIBIT 18

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 18

**KURIN’S MOTION *IN LIMINE* NO. 2 TO PRECLUDE EVIDENCE OR
ARGUMENT THAT PRE-PATENT ISSUANCE BEHAVIOR SUPPORTS A
FINDING OF WILLFULNESS**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

)
)
)
)
) C.A. No. 1:19-cv-00097-CFC
) (CJB)
)
)
)
)
)
)

**KURIN’S MOTION *IN LIMINE* NO. 2 TO PRECLUDE EVIDENCE OR
ARGUMENT THAT PRE-PATENT ISSUANCE BEHAVIOR SUPPORTS A
FINDING OF WILLFULNESS**

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &

GARRISON LLP

1285 Avenue of the Americas

New York, NY 10019-6064

(212) 373-3000

Attorneys for Defendant Kurin, Inc.

May 17, 2022

TABLE OF AUTHORITIES

	Page(s)
 Cases	
<i>Am. Tech. Ceramics Corp. v. Presidio Components, Inc.</i> , 2019 WL 2330855 (E.D.N.Y. May 31, 2019)	1, 2, 3
<i>Bioverativ Inc. v. Behring LLC</i> , 2020 WL 1332921 (D. Del. Mar. 23, 2020)	1
<i>Gustafson, Inc. v. Intersys. Indus. Prods., Inc.</i> , 897 F.2d 508 (Fed. Cir. 1990).....	1
<i>Halo Elecs., Inc. v. Pulse Elecs., Inc.</i> , 579 U.S. 93 (2016).....	1
<i>Insituform Techs., Inc. v. Cat Contracting, Inc.</i> , 161 F.3d 688 (Fed. Cir. 1998).....	1
<i>Iron Grip Barbell Co., Inc. v. USA Sports, Inc.</i> , 392 F.3d 1317 (Fed. Cir. 2004).....	1
<i>Milgo Elec. Corp. v. United Bus. Commc’ns, Inc.</i> , 623 F.2d 645 (10th Cir. 1980)	2
<i>Plexxikon Inc. v. Novartis Pharms. Corp.</i> , 2021 WL 2224267 (N.D. Cal. June 2, 2021)	3
<i>Sonos, Inc. v. D&M Holdings Inc.</i> , 2017 WL 5633204 (D. Del. Nov. 21, 2017)	2
<i>Sri Int’l, Inc. v. Cisco Sys., Inc.</i> , 930 F.3d 1295 (Fed. Cir. 2019).....	1
<i>State Indus., Inc. v. A.O. Smith Corp.</i> , 751 F.2d 1226 (Fed. Cir. 1985).....	1, 2, 3
 Other Authorities	
Fed. R. Evid. 401	1
Fed. R. Evid. 402	1, 2, 3
Fed. R. Evid. 403	1, 2, 3

Pursuant to Federal Rules of Evidence 401–403, Magnolia should be precluded from introducing any evidence or argument on acts pre-issuance in support of its willfulness claims.¹ “[C]ulpability is generally measured against the knowledge of the actor at the time of the challenged conduct.” *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 105 (2016). “To willfully infringe a *patent*, the patent must exist.” *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985); *Gustafson, Inc. v. Intersys. Indus. Prods., Inc.*, 897 F.2d 508, 510–11 (Fed. Cir. 1990); *Bioverativ Inc. v. Behring LLC*, 2020 WL 1332921, *2 (D. Del. Mar. 23, 2020). Accordingly, the pre-patent issuance evidence here is irrelevant under *Halo* to Kurin’s culpability and “may not be offered to prove willful infringement” *Am. Tech. Ceramics Corp. v. Presidio Components, Inc.*, 2019 WL 2330855, at *11 (E.D.N.Y. May 31, 2019); *Sri Int’l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1308 (Fed. Cir. 2019).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ This evidence is also irrelevant to inducement or secondary considerations. *See Insituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 695 (Fed. Cir. 1998); *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004).

[REDACTED]

[REDACTED]. Kurin disputes many of these assertions, but even if true they are all irrelevant to whether Kurin willfully infringed *the patents-in-suit*, which issued after this alleged behavior. *Am. Tech.*, 2019 WL 2330855, at *11. Such irrelevant evidence is however, very likely to be unfairly prejudicial to a jury. Thus, Magnolia should be precluded from offering this evidence under FRE 402 and 403.

Magnolia's first two categories of such evidence, [REDACTED]
[REDACTED], are related and fail for the same reasons. First, [REDACTED] is irrelevant to whether Kurin willfully infringed the specific claims at issue here. *See* Ex. 1, at 46:6–23; *State Indus.*, 751 F.2d at 1235–37.

Second, even assuming, *arguendo*, [REDACTED]
[REDACTED]
[REDACTED]” *Milgo Elec. Corp. v. United Bus. Commc'ns, Inc.*, 623 F.2d 645, 666 (10th Cir. 1980); *State Indus.*, 751 F.2d at 1236; *Sonos, Inc. v. D&M Holdings Inc.*, 2017 WL 5633204, at *4 (D. Del. Nov. 21, 2017). [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] And, even for the asserted patents, Magnolia

relies on the doctrine of equivalents for key limitations. *See, e.g.*, Ex. 4 at 6, 20, 50–55; Ex. 5 at 21, 27, 29, 35. Thus, Kurin successfully developed a product outside the scope of the then-existing Magnolia patent portfolio, exactly what the patent system encourages. *State Indus.*, 751 F.2d at 1236.

The unfair prejudice Magnolia’s “evidence” will cause far outweighs its nonexistent probative value. *See, e.g., Plexxikon Inc. v. Novartis Pharms. Corp.*, 2021 WL 2224267, at *5–6, 8 (N.D. Cal. June 2, 2021) (excluding evidence of alleged copying of related patent applications, which “notably did not result in infringement of the related patents” under FRE 403).

The third category, [REDACTED] also has no probative value—[REDACTED]

[REDACTED] Ex. 6 at 14–16. The fourth category, [REDACTED]

[REDACTED]

[REDACTED] These *pre-issuance* acts have no bearing on patent infringement, and are being offered by Magnolia only in an attempt to unfairly prejudice the jury against Kurin.

This “evidence” has no probative value and is improper evidence that should be excluded under FRE 402 and 403. *See, e.g., Plexxikon*, 2021 WL 2224267, at *8; *Am. Tech.*, 2019 WL 2330855, at *11. For the foregoing reasons, the Court should grant this motion *in limine*.

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP

1285 Avenue of the Americas

New York, NY 10019-6064

(212) 373-3000

ngroombridge@paulweiss.com

cnyarady@paulweiss.com

kraman@paulweiss.com

jreich@paulweiss.com

abarel@paulweiss.com

RICHARDS, LAYTON & FINGER,
P.A.

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)

Richards, Layton & Finger, P.A.

920 N. King Street

One Rodney Square

Wilmington, DE 19801

(302) 651-7700

Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

May 17, 2022

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**DECLARATION OF ARIELLA BAREL IN SUPPORT
OF KURIN, INC.'S MOTION *IN LIMINE* NO. 2 TO PRECLUDE
EVIDENCE OR ARGUMENT THAT PRE-ISSUANCE
BEHAVIOR SUPPORTS A FINDING OF WILLFULNESS**

I, Ariella Barel, declare as follows:

I am a member in good standing of the bar of the State of New York, First Department and am associated with Paul, Weiss, Rifkind, Wharton & Garrison LLP, counsel for Defendant Kurin, Inc. (“Kurin”) in this action. I have been admitted *pro hac vice* for this matter. I respectfully submit this Declaration in support of Kurin’s Motion *in Limine*, which is filed herewith.

1. Attached hereto as **Exhibit 1** is a true and correct copy of an excerpt of the transcript of the December 10, 2020 Hearing on Magnolia's Motion to Amend.

2. Attached hereto as **Exhibit 2** is a true and correct copy of the Kurin website page entitled “Kurin Lock” as of May 13, 2022.

3. Attached hereto as **Exhibit 3** is a true and correct copy of an image taken at timestamp 2:09 from the video entitled “SteriPath - Mark Rupp MD FINAL SD.mp4” and bearing Bates number MAG-DEL0003116, dated June 6, 2017.

4. Attached hereto as **Exhibit 4** is a true and correct copy of an excerpt of Attachment A to Magnolia’s First Amended Infringement Contentions, dated July 17, 2020.

5. Attached hereto as **Exhibit 5** is a true and correct copy of an excerpt of Attachment B to Magnolia’s First Amended Infringement Contentions, dated July 17, 2020.

6. Attached hereto as **Exhibit 6** is a true and correct copy of an excerpt of Magnolia’s First Amended Infringement Contentions, dated July 17, 2020.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on May 17, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL)
TECHNOLOGIES, INC.,)
Plaintiff,) Civil Action No.
v.) 19-97-CFC-CJB
KURIN, INC.,)
Defendant.)

Thursday, December 10, 2020
3:00 p.m.
Teleconference

BEFORE: THE HONORABLE JENNIFER L. HALL
United States Magistrate Judge

APPEARANCES:

FISH & RICHARDSON
BY: DOUGLAS E. McCANN, ESQ.
JUANITA BROOKS, ESQ.

Counsel for the Plaintiff

1 APPEARANCES, CONTINUED:

2
3 MORRIS JAMES LLP
4 BY: CORTLAN S. HITCH, ESQ.

5 - and -

6 TURNER BOYD
7 BY: KAREN BOYD, ESQ.

8 - and -

9 X-PATENTS
10 BY: JONATHAN HANGARTNER, ESQ.

11 Counsel for the Defendant

12 - - - - -
13
14
15
16
17
18
19
20
21
22
23
24

1 in a case that's not going to be tried for
2 another year, until October.

3 And that's one of the reasons we
4 pointed to the Pennypack factors, Your Honor.
5 The Third Circuit, I think generally when
6 you're talking about whether evidence should
7 or should not be excluded from a case, the
8 Third Circuit's Pennypack factors I think send
9 a really strong message the default should be
10 included, and it should be a fairly extreme
11 set of circumstances where a court will throw
12 something out. And, you know, on the eve of
13 trial, that could be something different, but
14 that's not what we're talking about here.

15 Just briefly, Your Honor, on the
16 other two issues, willfulness and the, quote,
17 other stuff, unquote, with respect to
18 willfulness, Your Honor understands that in
19 order to show willful infringement, you have
20 to prove state of mind; you have to get inside
21 somebody's head. And that's not the kind of
22 thing that typically can be done with
23 information that's in the public domain. You
24 have to get discovery. You have to get the

1 internal documents and try to piece together a
2 story, probably a story based on
3 circumstantial as opposed to direct evidence,
4 which is always harder and more complicated to
5 do.

6 Now, we, in one of our elements
7 to prove willful infringement, we have to
8 prove knowledge of these specific patents, and
9 Magnolia has a number of patents, and we need
10 to show these specific two, they were aware of
11 those. And, of course, we tried to get direct
12 evidence by serving interrogatories saying
13 tell us when you first knew of the two
14 patents. And the answer for a long time in
15 this case is, we didn't know of them. And we
16 found that hard to believe, because, really,
17 both these companies sell one product, and
18 both of these companies considered each other
19 to be their main competitor. And so it was a
20 little -- and they're both small companies and
21 startups. So it was a little hard for us to
22 believe that Kurin simply had no idea of each
23 Magnolia patent as it issued.

24 But be that as it may, that was

1 the circumstances we were in in July of 2020.
2 So what we did was we drafted contentions
3 based on documents, most of which we've
4 received after May of 2020, to put together a
5 circumstantial case to show the state of mind
6 for willfulness, and that's what the gist of
7 those contentions are, Your Honor.

8 Now, as it happens, after those
9 contentions were served, the ones that are the
10 issue in this motion, Kurin did supplement
11 their interrogatories to say we actually know,
12 we knew, they've admitted now they've known
13 about the one. I guess the point was with
14 respect to those interrogatories, we had to
15 construct that circumstantial case based on
16 their documents, which is not something we
17 would have had before the case began, and
18 which, as we laid out in the brief, most of
19 which came to us beginning in May of 2020.

20 Then, Your Honor, just the last
21 point, and I've touched on this a little bit
22 already, what I'm calling the other stuff.
23 You know, when you -- everything that was a
24 redline in those contentions became a dispute

1 State of Delaware)
2)
3 New Castle County)

4 CERTIFICATE OF REPORTER

5
6 I, Jennifer M. Guy, Registered
7 Professional Reporter and Notary Public in the
8 State of Delaware, do hereby certify that the
9 foregoing record, Pages 1 to 120 inclusive, is
10 a true and accurate record of the
11 above-captioned proceedings held on the 10th
12 day of December, 2020, in Wilmington.

13
14
15 /S/ Jennifer M. Guy, RPR
16 Jennifer M. Guy, RPR
17
18
19
20
21
22
23
24

EXHIBIT 2



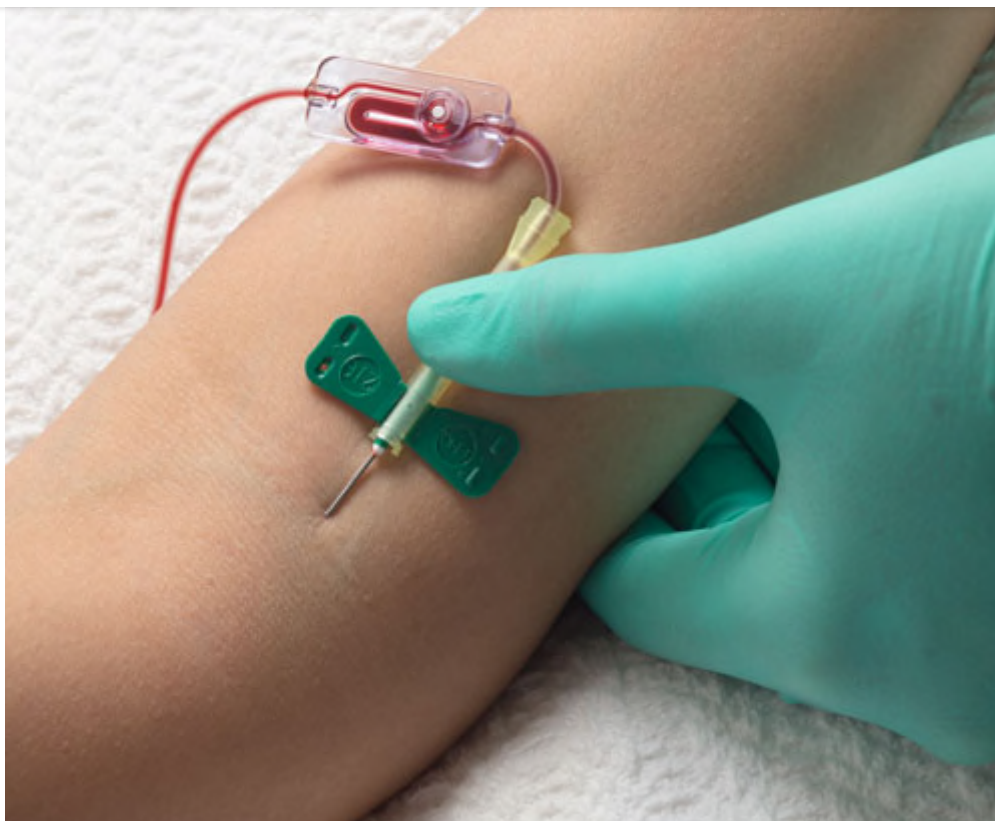
Kurin Lock®

The SIMPLE Solution for Improved Blood Culture Collection

FDA 510(k) Cleared

The patented Kurin Lock with Flash Technology transforms a regular blood culture collection set into a powerful yet simple way to put skin contaminants on the sideline. Each Kurin® collection set features industry-leading butterfly needles and is compatible with all major blood culture bottles. The integrated Kurin Lock® enables clinicians to sideline the initial flash of blood, which may contain skin microbes, with no change in collection practice.

Venipuncture



Perform standard venipuncture procedure with a butterfly needle.

Syringe Draws



The detachable bottle holder allows the connection of a syringe for gentle draws on hard to stick patients.

Freshly-placed PIVs



Per hospital protocol, the male luer connector of the Kurin PIV™ collection set enables draws from freshly placed peripheral catheters.

ML-013 Rev D

Copyright © 2022 Kurin Inc. All rights reserved.

[Privacy Policy](#)

We and selected third parties use cookies or similar technologies as specified in our privacy policy. You can consent to the use of such technologies by closing this notice, by interacting with any link or button outside of this notice or by continuing to browse otherwise.



How we use cookies

We may request cookies to be set on your device. We use cookies to let us know when you visit our websites, how you interact with us, to enrich your user experience, and to customize your relationship with our website.

Click on the different category headings to find out more. You can also change some of your preferences. Note that blocking some types of cookies may impact your experience on our websites and the services we are able to offer.

Essential Website Cookies

These cookies are strictly necessary to provide you with services available through our website and to use some of its features.

Because these cookies are strictly necessary to deliver the website, refusing them will have impact how our site functions. You always can block or delete cookies by changing your browser settings and force blocking all cookies on this website. But this will always prompt you to accept/refuse cookies when revisiting our site.

We fully respect if you want to refuse cookies but to avoid asking you again and again kindly allow us to store a cookie for that. You are free to opt out any time or opt in for other cookies to get a better experience. If you refuse cookies we will remove all set cookies in our domain.



modify cookies from other domains. You can check these in your browser security settings.

Google Analytics Cookies

These cookies collect information that is used either in aggregate form to help us understand how our website is being used or how effective our marketing campaigns are, or to help us customize our website and application for you in order to enhance your experience.

If you do not want that we track your visit to our site you can disable tracking in your browser here:

Other external services

We also use different external services like Google Webfonts, Google Maps, and external Video providers. Since these providers may collect personal data like your IP address we allow you to block them here. Please be aware that this might heavily reduce the functionality and appearance of our site. Changes will take effect once you reload the page.

Google Webfont Settings:



Google reCaptcha Settings:

Vimeo and Youtube video embeds:

Other cookies

The following cookies are also needed - You can choose if you want to allow them:

Privacy Policy

You can read about our cookies and privacy settings in detail on our Privacy Policy Page.

[Privacy Policy](#)

Accept settings Hide notification only

EXHIBIT 3



EXHIBIT 4

ATTACHMENT A

CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER

Attachment A - Infringement of U.S. Patent No. 9,855,001

This chart applies the claims of Magnolia's U.S. Patent No. 9,855,001 ("the '001 patent") against Kurin's blood culture collection sets numbered K-11221, K-11223, K-11225, D-11221, D-21223, D-11223, M-11221, M-21223, M-11223, M-21223, T-11221, T-21221, T-11223, T-21223, D-PIV12, D-PIV18, M-PIV12, M-PIV18, T-PIV12, T-PIV18, S-PIV4, and S-PIV10, (collectively, "the Accused Products").¹

Based on the information Kurin has provided to date, it is Magnolia's understanding that Accused Products K-11221, K-11223, K-11225 are models submitted to the FDA for approval. March 22, 2016 Email Re Kurin Numbering System [KUR-MAG-DE294038]. It is also Magnolia's understanding that one or more of these "K" versions of the Kurin Lock did not include the umbrella valve that is present in the Kurin Lock device that is commercially available today, however, in all other respects those earlier "K" versions that did not include the umbrella valve were the same or substantially similar to the current, commercially available Kurin Lock device.

The Accused Products are substantially similar to one another. D.I. 59 at 4 (Kurin stating that "Magnolia asserted 82 claims – later reduced to 44 – targeting a single Kurin device."). Each of the Accused Products includes a Kurin Lock device. *See, e.g.*, MAG-DE0000688–693 (<https://www.kurin.com/skin-contaminant-diversion/>) at 688 ("The Kurin Lock® - Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful specimen diversion device that automates diversion during the routine process of drawing a blood culture."). Kurin's website includes a "How it Works" page that includes a single animation that purports to describe and depict the operation of the Kurin Blood Collection Set that includes the Kurin Lock device. (<https://www.kurin.com/skin-contaminant-discard/>). The listing of Accused Products is intended to be a list of all commercially available versions of Kurin's blood culture collection sets.

Based on the information presently available to Magnolia, the Kurin Lock device consists of five (5) individual parts. *See* Dkt. 94, Declaration of Jonathan Hangartner in Support of Kurin's Samples of the Accused Product; 2020-07-01 Motion for Leave Hearing Transcript. As described in the Hangartner Declaration, those five components are a top plate, a bottom plate, a cap, an umbrella valve and a porous plug. *Id.* *See also* Kurin Drawing Numbers KUR-2005 (Top Housing) [KUR-MAG-DE001623-24], KUR-2006 (Bottom Housing) [KUR-MAG-DE001625-26], KUR-2007 (Cap) [KUR-MAG-DE001627], KUR-6010 (Hydrophobic Self-Sealing Plug) [KUR-MAG-DE001655], KUR-6011 (Umbrella Valve) [KUR-MAG-DE001656], and KUR-8036 (Assembly) [KUR-MAG-DE001659], MiniValve Part Number UM 053.002 SD (Umbrella Valve and seating suggestion) [KUR-MAG-DE003703];

¹ To the extent Kurin is selling other blood culture collection sets that use the Kurin Lock device, Magnolia accuses those versions as well and the analysis in this chart applies to those versions.

Attachment A

Manufacturing Procedure MP-016 [KUR-MAG-DE000104-124] and the duplicates of these drawings produced throughout KUR-MAG-DE000138-2362. A table (shown below) produced along with Kurin's engineering drawings shows that the same set of engineering drawings is for the Kurin Lock device found in every version of the Accused Product:

top level	D-11221	D-11223	D-21221	D-31223	D-PV12	D-PV18	M-11221	M-11223	M-21221	M-21223	M-PV12	M-PV18	T-11221	T-11223	T-21221	T-21223	T-PV12	T-PV18	S-PV10	S-PV18
IFU	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090	KUR-4091
inner box label	KUR-4009	KUR-4010	KUR-4018	KUR-4021	KUR-4029	KUR-4076	KUR-4011	KUR-4012	KUR-4016	KUR-4027	KUR-4042	KUR-4079	KUR-4049	KUR-4052	KUR-4055	KUR-4058	KUR-4046	KUR-4082	KUR-4085	KUR-4088
shipper box label	KUR-4013	KUR-4014	KUR-4019	KUR-4022	KUR-4030	KUR-4077	KUR-4015	KUR-4016	KUR-4025	KUR-4028	KUR-4043	KUR-4080	KUR-4050	KUR-4053	KUR-4056	KUR-4059	KUR-4047	KUR-4083	KUR-4086	KUR-4089
tape	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003
inner carton	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003
shipper box	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004	KUR-5004
label	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001	KUR-5001
packaged device	KUR-8002	KUR-8023	KUR-8024	KUR-8025	KUR-8028	KUR-8038	KUR-8020	KUR-8021	KUR-8026	KUR-8027	KUR-8029	KUR-8037	KUR-8031	KUR-8032	KUR-8033	KUR-8034	KUR-8030	KUR-8039	KUR-8040	KUR-8041
adhesive	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001	KUR-3001
prod label	KUR-4005	KUR-4006	KUR-4017	KUR-4020	KUR-4038	KUR-4075	KUR-4007	KUR-4008	KUR-4013	KUR-4016	KUR-4041	KUR-4078	KUR-4048	KUR-4051	KUR-4054	KUR-4057	KUR-4045	KUR-4081	KUR-4084	KUR-4087
tray/pouch	KUR-5015	KUR-5015	KUR-5015	KUR-5015	KUR-5015	KUR-5015	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5016	KUR-5016	KUR-5015	KUR-5015	KUR-5015	KUR-5017	KUR-5017	KUR-5017
lid stock	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5018	KUR-5018	KUR-5018
collection adapter	KUR-6006	KUR-6006	KUR-6006	KUR-6006	KUR-6006	KUR-6006	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005
collection set	KUR-6008	KUR-6009	KUR-6012	KUR-6013			KUR-6008	KUR-6009	KUR-6012	KUR-6013			KUR-6008	KUR-6009	KUR-6012	KUR-6013				
luer adapter					KUR-6007	KUR-6007					KUR-6007	KUR-6007					KUR-6020	KUR-6020	KUR-6020	KUR-6020
male luer					KUR-6020	KUR-6020					KUR-6020	KUR-6020					KUR-6021	KUR-6021	KUR-6021	KUR-6021
female luer					KUR-6021	KUR-6021					KUR-6021	KUR-6021					KUR-6022	KUR-6022	KUR-6022	KUR-6022
vented cap for male luer					KUR-6022	KUR-6022					KUR-6022	KUR-6022					KUR-6023-1	KUR-6023-1	KUR-6023-1	KUR-6023-1
tubing					KUR-6023-1	KUR-6023-1					KUR-6023-1	KUR-6023-1					KUR-6023-9	KUR-6023-9	KUR-6023-9	KUR-6023-9
extension set					KUR-6023-9	KUR-6023-9					KUR-6023-9	KUR-6023-9					KUR-6025	KUR-6025	KUR-6025	KUR-6025
cap for female luer					KUR-6025	KUR-6025					KUR-6025	KUR-6025					KUR-6025	KUR-6025	KUR-6025	KUR-6025
lock	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036	KUR-8036
top housing	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005
btm housing	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006
cap	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007	KUR-2007
adhesive	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000
lubricant	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002
plug	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010
valve	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011

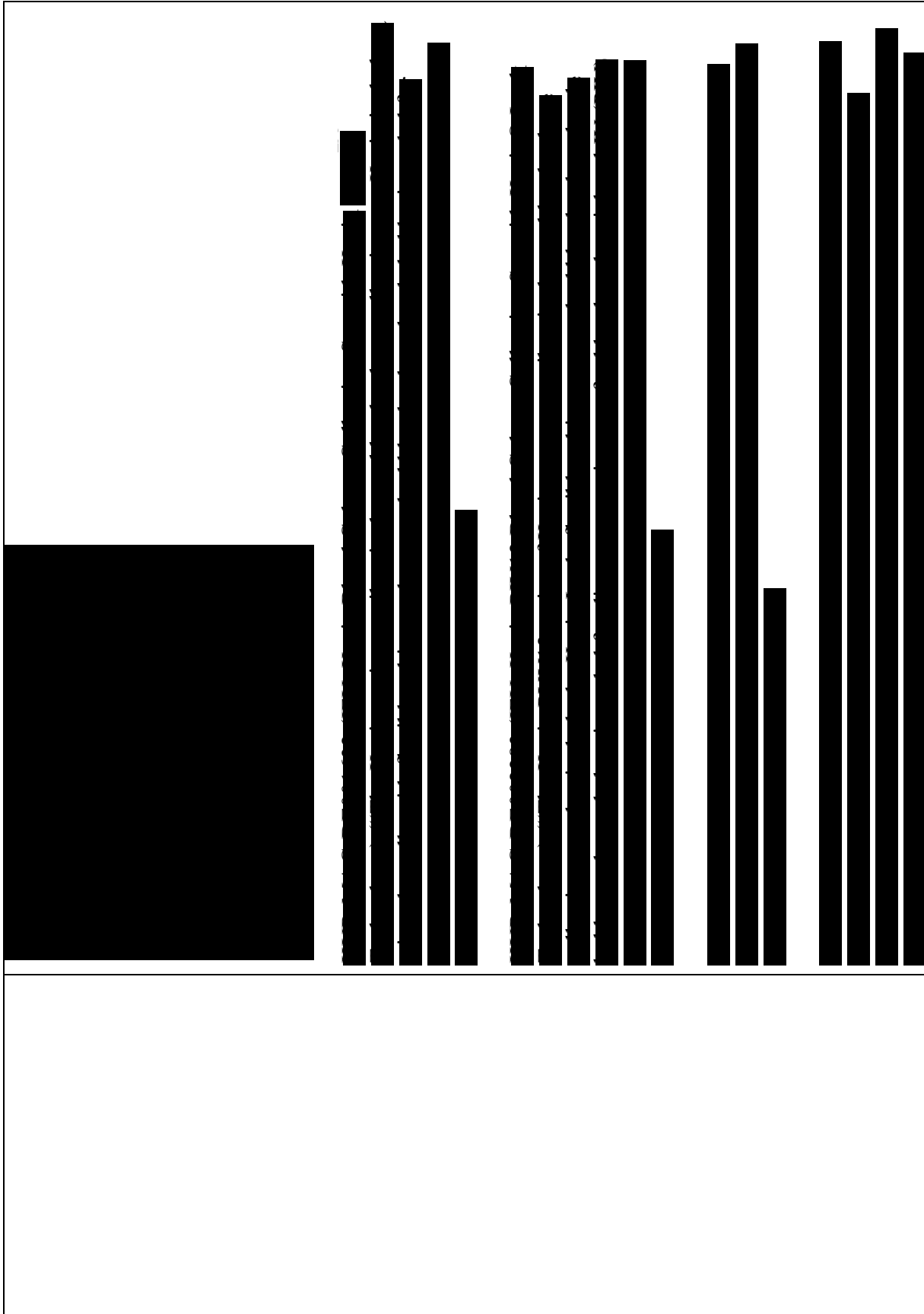
KUR-MAG-DE0001621 (boxed to show the Kurin Lock device schematics are the same for all Accused Products).

As such, Magnolia contends that, for purposes of the infringement analysis, the Accused Products are identical except where otherwise indicated below. Magnolia reserves its right to amend these contentions as additional information becomes available.

In addition to the exemplary documents provided in the chart, Magnolia also relies on and/or reserves the right to rely on the 510(k) submissions for the Accused Products produced by Kurin at KUR-MAG-DE000137 through KUR-MAG-DE001620, the engineering drawings for the Accused Products produced by Kurin at KUR-MAG-DE001621 through KUR-MAG-DE001869, and Kurin's patent applications describing the Accused Products, including U.S. Patent Appl. Pub. 2018/0271425 [MAG-DEL0000720].

Claim 1	Accused Products
1. An apparatus for obtaining a bodily fluid sample from a	Each of the Accused Products is an apparatus for obtaining a bodily fluid sample from a patient with reduced contamination. <i>See, e.g.,</i>

Attachment A



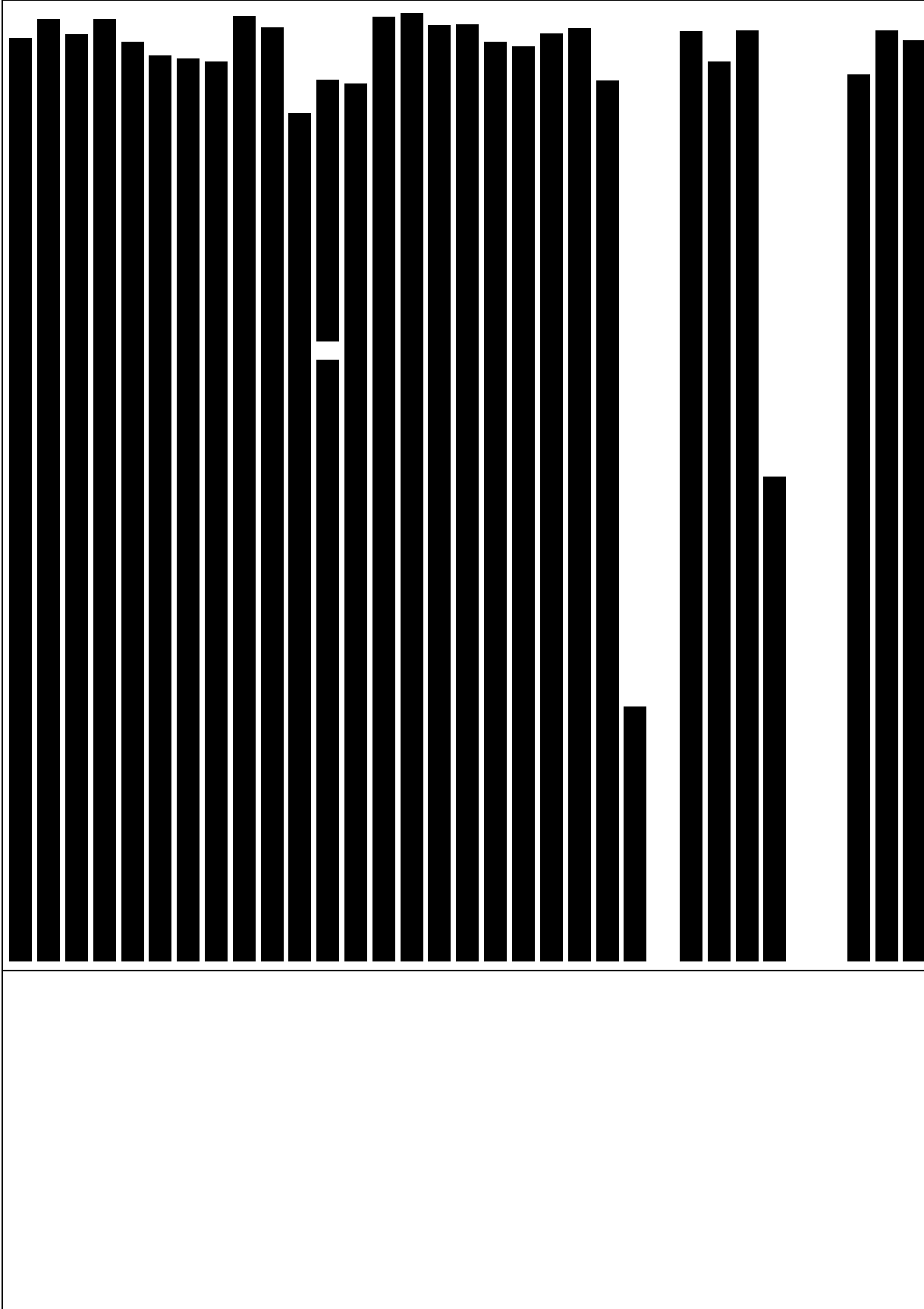
Attachment A

<div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>

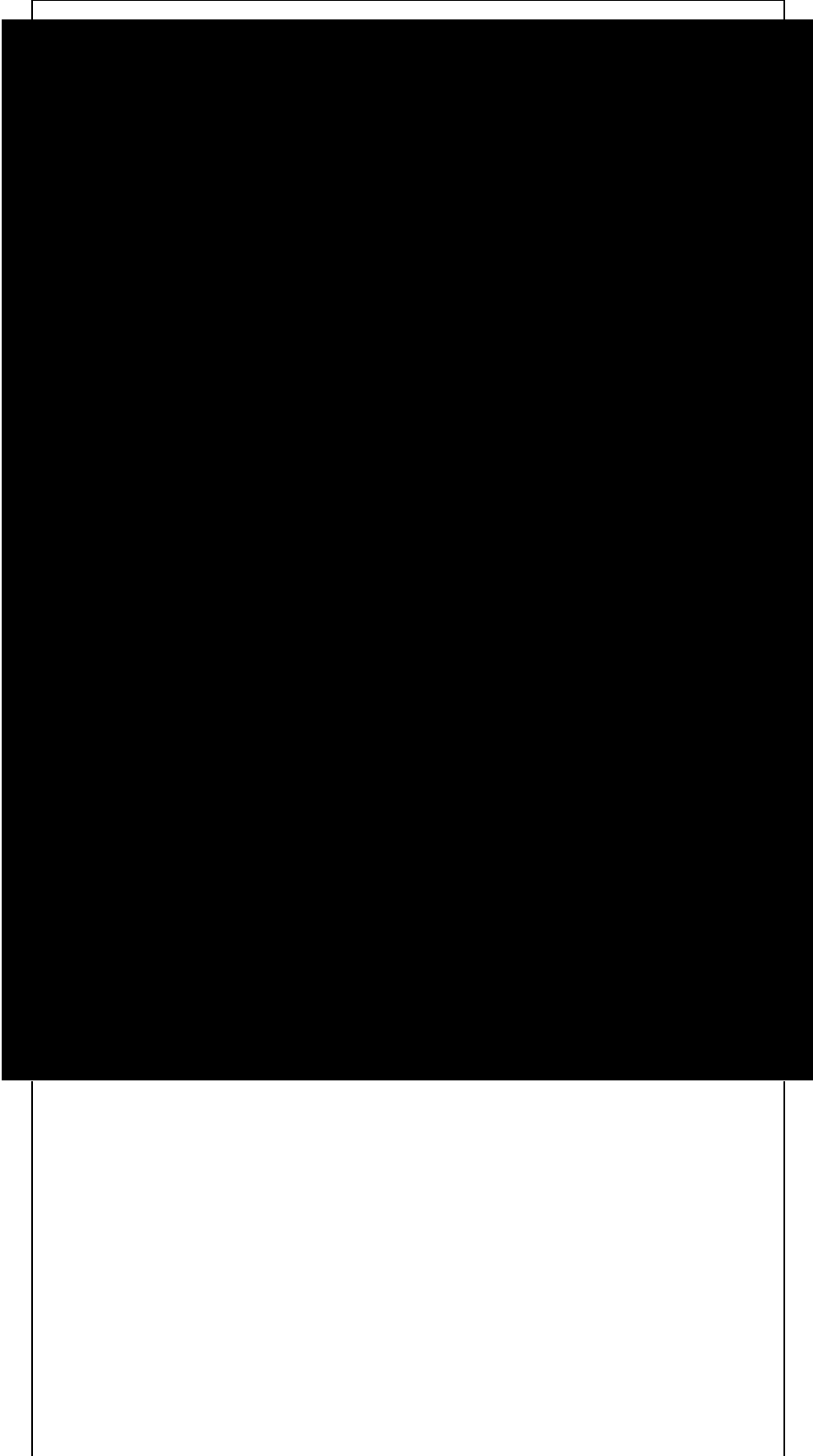
Attachment A

<div>[REDACTED]</div>	
<div>[REDACTED]</div>	

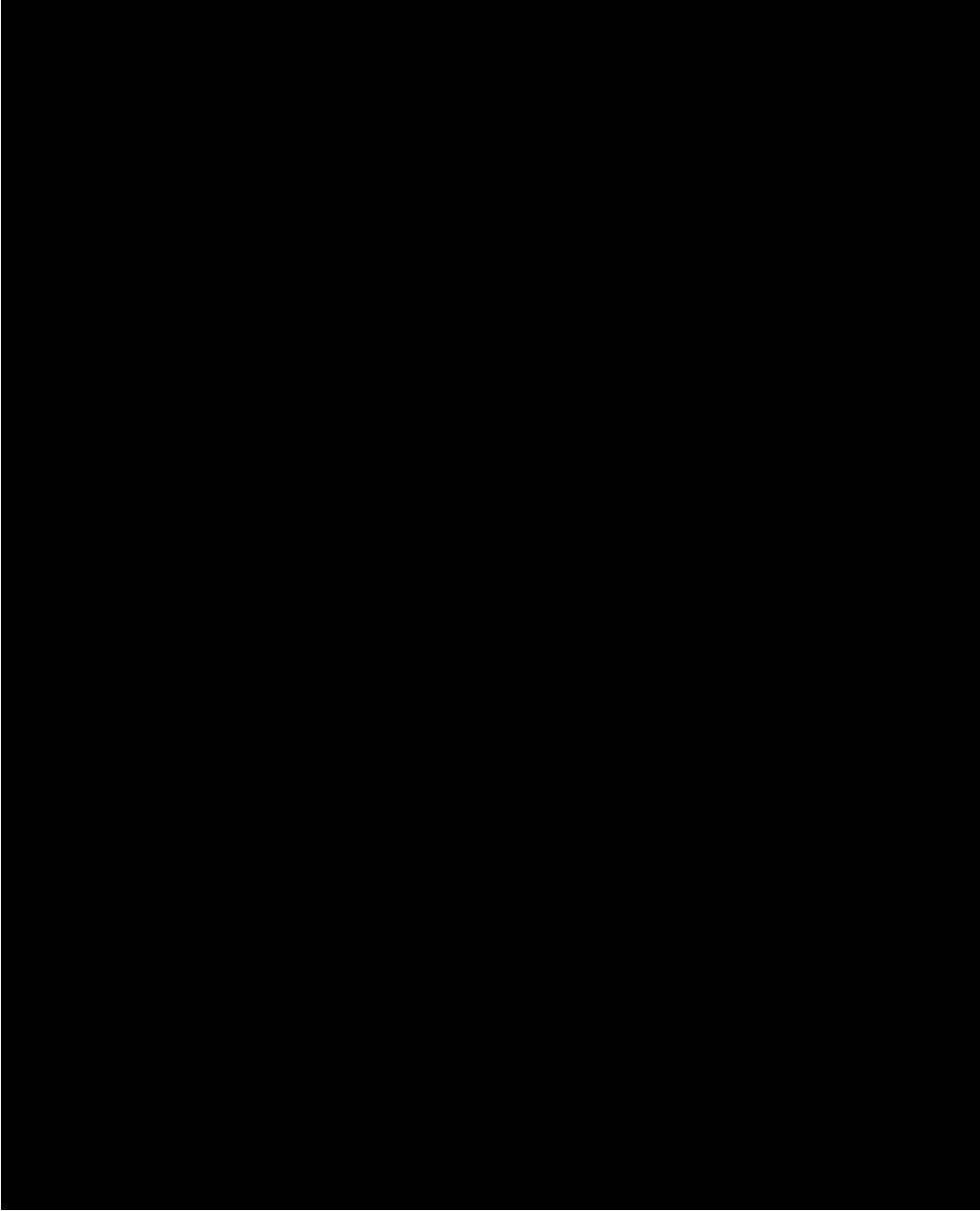
Attachment A



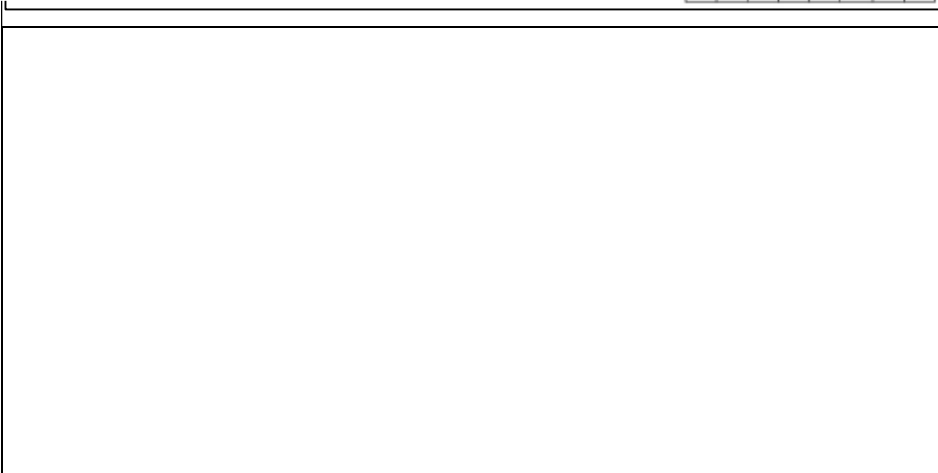
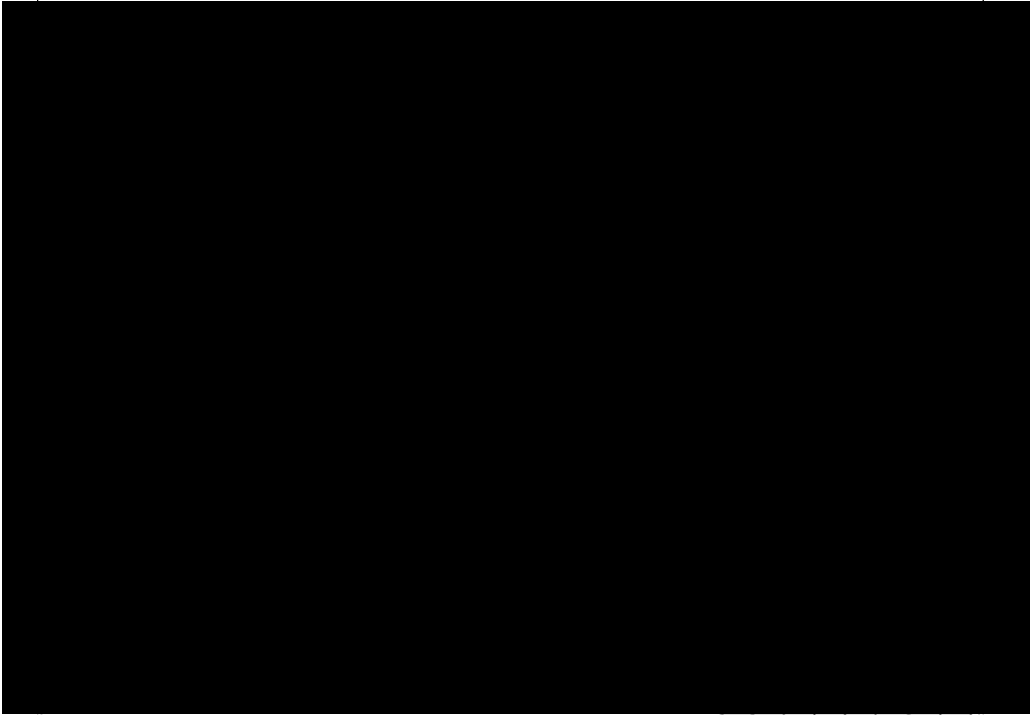
Attachment A



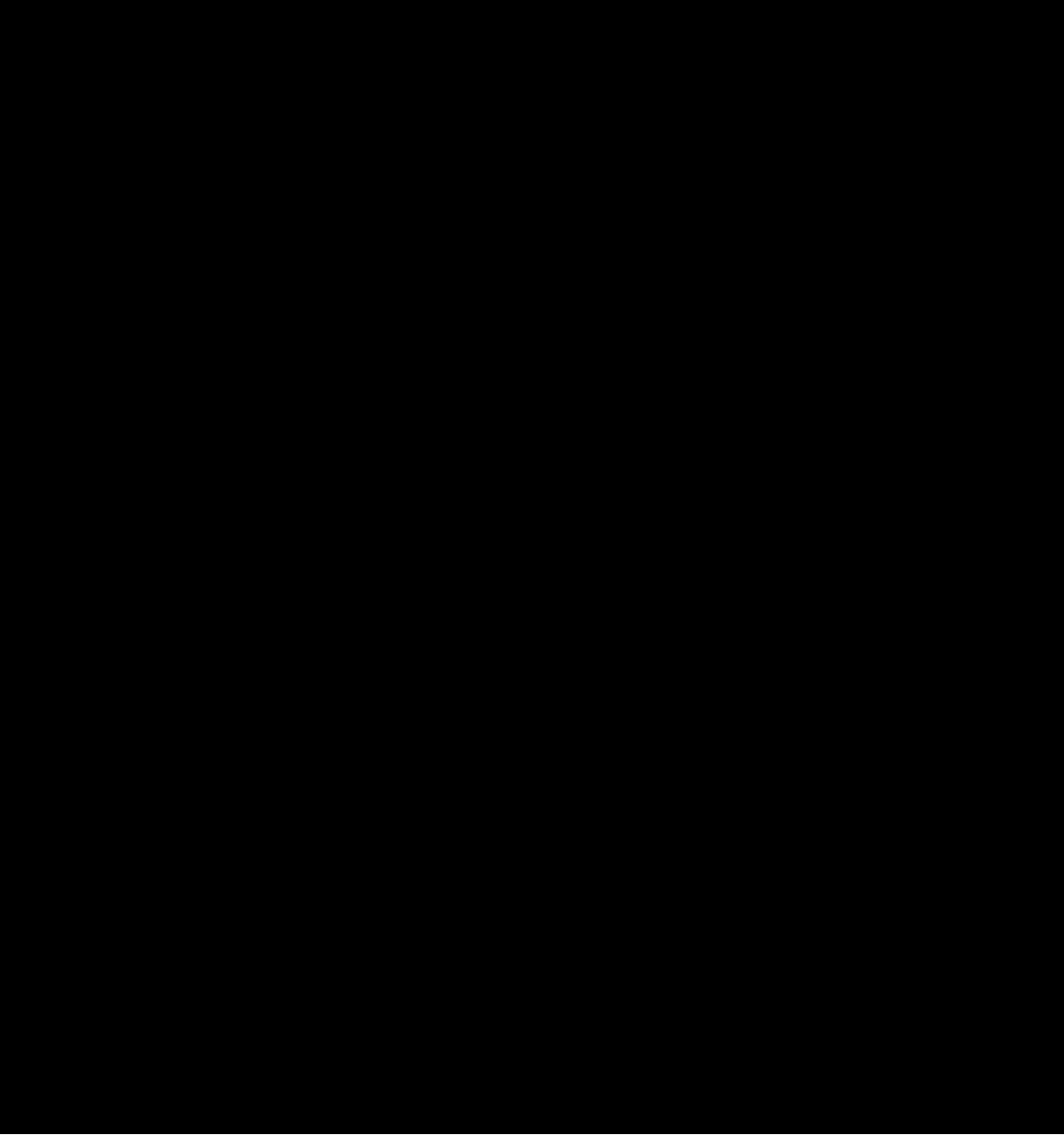
Attachment A



Attachment A



Attachment A



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT 5

FILED UNDER SEAL

EXHIBIT 6

FILED UNDER SEAL

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 18

**MAGNOLIA’S OPPOSITION TO KURIN’S MOTION *IN LIMINE* NO. 2:
TO PRECLUDE EVIDENCE OR ARGUMENT THAT PRE-PATENT
ISSUANCE BEHAVIOR SUPPORTS A FINDING OF WILLFULNESS**

Kurin’s Motion *in Limine* No. 2 makes the same arguments as its Motion for Summary Judgment of No Enhanced Damages that the Court denied. D.I. 305 at 1–2; D.I. 396. The Court should deny the present motion as well.

Numerous courts, including the Federal Circuit and this District, have held that pre-issuance conduct may support post-issuance willfulness. *E.g.*, *Minn. Min. and Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1581 (Fed. Cir. 1992) (“[A]lthough willfulness is generally based on conduct that occurred after a patent issued, pre-patent conduct may also be used to support a finding of willfulness.”); *Kaufman Co., Inc. v. Lantech, Inc.*, 807 F.2d 970, 978–79 (Fed. Cir. 1986) (holding that willfulness is determined based on “the totality of the circumstances” and rejecting argument that “the allegedly improper copying took place before the patent was issued and therefore cannot be considered”). Indeed, in *Sonos, Inc. v. D&M Holdings Inc.*, Judge Bryson surveyed cases addressing this precise question and concluded that evidence of “particularly egregious behavior”—such as Kurin’s here—is relevant and admissible. C.A. No. 14-1330-WCB, 2017 WL 5633204, at *4 (D. Del. Nov. 21, 2017); *see also Idenix Pharms. LLC v. Gilead Scis., Inc.*, C.A. No. 13-1987-LPS, 2016 WL 7380530, at *1 (D. Del. Dec. 4, 2016); *Chimie v. PPG Indus., Inc.*, 218 F.R.D. 416, 422 (D. Del. 2003).

Kurin ignores these cases, and the cases it does cite are inapposite. Mot. at 1. For example, the Federal Circuit has rejected the interpretation of *State Industries*

that Kurin proposes. *Shiley, Inc. v. Bentley Lab'ys, Inc.*, 794 F.2d 1561, 1568 (Fed. Cir. 1986) (“*State* does not, as Bentley contends, hold that a finding of willful infringement can not stand whenever manufacture of an accused device begins prior to the issuance of a patent. On the contrary, *State* is in harmony with our prior and subsequent case law, which looks to the ‘totality of the circumstances presented in the case.’”). Similarly, in *Gustafson*, the Federal Circuit cited many of its own decisions sustaining willfulness based on pre-issuance conduct and held that “[w]hether an act is ‘willful’ is by definition a question of the actor’s intent, the answer to which must be inferred from all the circumstances.” *Gustafson, Inc. v. Intersystems Indus. Prod., Inc.*, 897 F.2d 508, 510–11 (Fed. Cir. 1990).

This is not a case where Kurin simply conducted competitive intelligence gathering on an unpatented product, as Kurin suggests in its brief. Mot. at 2–3; *cf. Bioverativ Inc. v. CSL Behring LLC*, C.A. No. 17-914-RGA, 2020 WL 1332921, at *3 (D. Del. Mar. 23, 2020) (excluding evidence of misappropriation of information regarding an unpatented product before the patents’ priority date). There is no dispute that the patents-in-suit claim priority to applications filed before Kurin was even founded and that Magnolia’s Steripath product practices the asserted claims.

As Magnolia explained in its opposition to Kurin’s Motion for Summary Judgment, [REDACTED]

[REDACTED]

See D.I. 344 at 2–7.

D.I. 346, Ex. 1 at 521:6–20. This entire course of conduct is relevant to Kurin’s knowledge and state of mind when the patents-in-suit issued and whether Kurin’s infringement of them after that date was willful. While the evidence may be prejudicial to Kurin, there is no *unfair* prejudice, especially because the Court has bifurcated the issue of willfulness from infringement. And the conduct plainly rises to the level that may be presented to the jury so that it may consider “the totality of the circumstances.” See D.I. 344 at 2–7; *Sonos*, 2017 WL 5633204, at *4; *Chimie*, 218 F.R.D. 416, at 422.

Finally, Kurin’s pre-issuance conduct is independently relevant to secondary considerations of non-obviousness. While Kurin claims in a footnote that it is not, the case it cites does not support that proposition. Mot. at 1 n.1 (citing *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). To the contrary, in *Minnesota Mining*, the Federal Circuit relied on pre-issuance conduct including copying in its discussion of secondary considerations. 976 F.2d at 1575. The evidence should be admitted for this reason as well.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**KURIN'S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 2 TO
PRECLUDE EVIDENCE OR ARGUMENT THAT PRE-PATENT
ISSUANCE BEHAVIOR SUPPORTS A FINDING OF WILLFULNESS**

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP

1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000

Attorneys for Defendant Kurin, Inc.

June 3, 2022

First, this Court did not review Kurin’s Motion for Summary Judgment. D.I. 396. Second, courts, including in Magnolia’s inapposite cases, consider admitting evidence of pre-patent issuance conduct only when it is “particularly egregious”—under fact patterns entirely different from our case.¹ Not a single one of those cases involved these facts—asserted claims drafted exclusively *after* the defendant’s product was publicly available. Unsurprisingly then, Magnolia is unable to credibly explain how even a single piece of pre-issuance evidence it seeks to rely on could show “egregious” conduct [REDACTED]. Third, on secondary considerations, Magnolia alleges pre-issuance conduct is relevant only to [REDACTED]

[REDACTED]

[REDACTED] *Iron Grip Barbell Co. Inc. v. USA sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). [REDACTED]

[REDACTED]

[REDACTED] *See*, e.g. Ex. 7; Ex. 8 (entirely different types of structures identified for, e.g., reservoir).

¹ In *Sonos*, the factual allegations were not before Judge Bryson, and he ordered the plaintiff to provide a detailed account of “any such evidence or argument” before offering it. 2017 WL 5633204, at *4. In *3M*, the defendant stole and attempted to patent trade secrets while plaintiff’s patents were pending and faithfully copied other products. *Kaufman* also involved a faithful copy. In *Idenix* the court only ruled that pre-patent conduct was not “absolutely preclude[d].” 2016 WL 7380530, at *1. *Chimie* was an order to log pre-patent communications.

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP

1285 Avenue of the Americas

New York, NY 10019-6064

(212) 373-3000

ngroombridge@paulweiss.com

cnyarady@paulweiss.com

kraman@paulweiss.com

jreich@paulweiss.com

abarel@paulweiss.com

RICHARDS, LAYTON & FINGER,
P.A.

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)

Richards, Layton & Finger, P.A.

920 N. King Street

One Rodney Square

Wilmington, DE 19801

(302) 651-7700

Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

June 3, 2022

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**DECLARATION OF ARIELLA BAREL IN SUPPORT
OF KURIN, INC.'S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE*
NO. 2 TO PRECLUDE EVIDENCE OR ARGUMENT THAT PRE-
ISSUANCE BEHAVIOR SUPPORTS A FINDING OF WILLFULNESS**

I, Ariella Barel, declare as follows:

I am a member in good standing of the bar of the State of New York, First Department and am associated with Paul, Weiss, Rifkind, Wharton & Garrison LLP, counsel for Defendant Kurin, Inc. (“Kurin”) in this action. I have been admitted *pro hac vice* for this matter. I respectfully submit this Declaration in support of Kurin’s reply in support of its Motion *in Limine*, which is filed herewith.

1. Attached hereto as **Exhibit 7** is a true and correct copy of an excerpt of Attachment B to Magnolia's First Amended Infringement Contentions, dated July 17, 2020.

2. Attached hereto as **Exhibit 8** is a true and correct copy of an excerpt of Plaintiff Magnolia Medical Technologies, Inc.'s Amended Supplemental Objections and Responses to Defendant Kurin, Inc.'s Fourth Set of Interrogatories (No. 11), dated December 1, 2020.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on June 3, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 7

FILED UNDER SEAL

EXHIBIT 8

FILED UNDER SEAL

EXHIBIT 19

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 19

KURIN’S MOTION *IN LIMINE* NO. 3 TO EXCLUDE EVIDENCE OR ARGUMENT THAT KURIN’S WORD CHOICE IN MARKETING OR REGULATORY DOCUMENTS IS EVIDENCE OF INFRINGEMENT

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**KURIN’S MOTION *IN LIMINE* NO. 3 TO EXCLUDE EVIDENCE OR
ARGUMENT THAT KURIN’S WORD CHOICE IN MARKETING OR
REGULATORY DOCUMENTS IS EVIDENCE OF INFRINGEMENT**

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

OF COUNSEL:

Nicholas Groombridge

Catherine Nyarady

Kripa Raman

Joshua D. Reich

Ariella Barel

PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP

1285 Avenue of the Americas

New York, NY 10019-6064

(212) 373-3000

Attorneys for Defendant Kurin, Inc.

May 17, 2022

TABLE OF AUTHORITIES

Page(s)

Cases

<i>Ferring Pharms. Inc. v. Par Pharm., Inc.</i> , 267 F. Supp. 3d 501 (D. Del. 2017).....	1, 2
<i>Intel. Corp. v. Tela Innovations, Inc.</i> , 2021 WL 1222622 (N.D. Cal. Feb. 11, 2021)	2
<i>Plastic Omnium Advanced Innovation & Rsch. v. Donghee Am., Inc.</i> , 943 F.3d 929 (Fed. Cir. 2019).....	2, 3

Other Authorities

Fed. R. Evid. 401	1
Fed. R. Evid. 402	1
Fed. R. Evid. 403	1

Pursuant to Federal Rules of Evidence 401–403, Magnolia should be precluded from introducing evidence or argument that [REDACTED]

[REDACTED] is evidence of infringement. Infringement requires the fact-finder to *compare the construed claims to the device at issue*. *Ferring Pharms. Inc. v. Par Pharm., Inc.*, 267 F. Supp. 3d 501, 503 (D. Del. 2017). Magnolia and its expert, Dr. Santiago, have had ample opportunity to study and test the device’s functionality, and compare this to the claim limitations. They should not be allowed to rely instead on descriptions untethered to the Court’s claim construction or the patents-in-suit, as infringement evidence. Such descriptions are irrelevant and unfairly prejudicial.

Magnolia and its expert have conducted testing and other direct analysis of how the Kurin device functions for purposes of analyzing infringement, including particularly the “diverter” and “sequester” claim limitations of the patents-in-suit. Because this most probative, direct evidence undermines Magnolia’s case, Magnolia and Dr. Santiago have sought to prop up their case improperly by pointing to Kurin’s descriptions of its product, many of which are public and antedate the filing of the claims in suit such that Magnolia could refer to them in drafting such claims.

Diverter: Magnolia’s infringement contentions and Dr. Santiago’s infringement report rely heavily on [REDACTED]

[REDACTED]. Ex. 1 ¶¶ 147–155.

But in this case, the term “diverter” was construed to be a means-plus-function limitation with a very specific meaning. D.I. 75 at 2. Unlike the testing evidence or other actual technical analysis of the accused product that reveals whether the accused product actually functions as such a “diverter”, Kurin’s *descriptions* of the device are irrelevant to whether it falls within the specific and narrow meaning accorded to this claim term. *Plastic Omnium Advanced Innovation & Rsch. v. Donghee Am., Inc.*, 943 F.3d 929, 935–36 (Fed. Cir. 2019) (defendant’s product literature using the term ‘parison’ could not establish whether construed claim term ‘extruded parison’ was met); *Ferring Pharms.*, 267 F. Supp. 3d at 507 (“The word defendant uses to characterize its own process is neither dispositive, nor even persuasive in the face of substantial evidence that its process employs [a different approach].”); *Intel. Corp. v. Tela Innovations, Inc.*, 2021 WL 1222622, at *4–5 (N.D. Cal. Feb. 11, 2021) (“[Defendant’s] internal nomenclature cannot change... its [process] or the agreed construction.”).

[REDACTED] and this evidence should not be presented to the jury. Any probative value is marginal at best, and would be far outweighed by the certainty of prejudice and confusion this evidence will cause—the jury will improperly treat Kurin’s descriptions as

admissions. Introduction of this evidence and testimony will taint the entire case.

Sequester: The same analysis applies to “sequester.” Magnolia and Dr. Santiago again rely on [REDACTED]
[REDACTED]
[REDACTED]” See Ex. 1 ¶¶ 180–183, *see also* ¶¶ 103, 107–118; Ex. 2 at 19, 27. But, the proper analysis is not how Kurin or its employees describe its device. *Plastic Omnium*, 943 F.3d at 935–36. Magnolia must demonstrate how the device satisfies the limitation. Inundating the jury with documents and testimony describing the device—as opposed to the readily available testing and other evidence that exists demonstrating whether the device actually “sequesters” as the claims require—is prejudicial for the same reasons as described above. [REDACTED]
[REDACTED]
[REDACTED]

Rather than demonstrate how the device satisfies the limitations *within the meaning of the asserted claims*, it appears that Magnolia and Dr. Santiago will rely on [REDACTED] to convince the jury that Kurin admitted its product diverts and sequesters to disguise the holes in its case. This approach is improper and highly prejudicial.

For the foregoing reasons, the Court should grant this motion *in limine*.

RICHARDS, LAYTON & FINGER,
P.A.

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
kraman@paulweiss.com
jreich@paulweiss.com
abarel@paulweiss.com

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

May 17, 2022

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**DECLARATION OF ARIELLA BAREL IN SUPPORT OF
KURIN, INC.'S MOTION *IN LIMINE* NO. 3 TO EXCLUDE EVIDENCE
OR ARGUMENT THAT KURIN'S WORD CHOICE IN MARKETING OR
REGULATORY DOCUMENTS IS EVIDENCE OF INFRINGEMENT**

I, Ariella Barel, declare as follows:

I am a member in good standing of the bar of the State of New York, First Department and am associated with Paul, Weiss, Rifkind, Wharton & Garrison LLP, counsel for Defendant Kurin, Inc. (“Kurin”) in this action. I have been admitted *pro hac vice* for this matter. I respectfully submit this Declaration in support of Kurin’s Motion *in Limine*, which is filed herewith.

1. Attached hereto as **Exhibit 1** is a true and correct copy of an excerpt of the Opening Expert Report of Dr. Juan G. Santiago Regarding Infringement of U.S. Patent Nos. 9,855,001 and 10,039,483, dated January 15, 2021.

2. Attached hereto as **Exhibit 2** is a true and correct copy of an excerpt of Attachment A to Magnolia's Infringement Contentions, dated July 17, 2020.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 17, 2022.

/s/ Ariella Barel
Ariella Barel

2. Attached hereto as **Exhibit 2** is a true and correct copy of an excerpt of Attachment A to Magnolia's Infringement Contentions, dated July 17, 2020.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 17, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

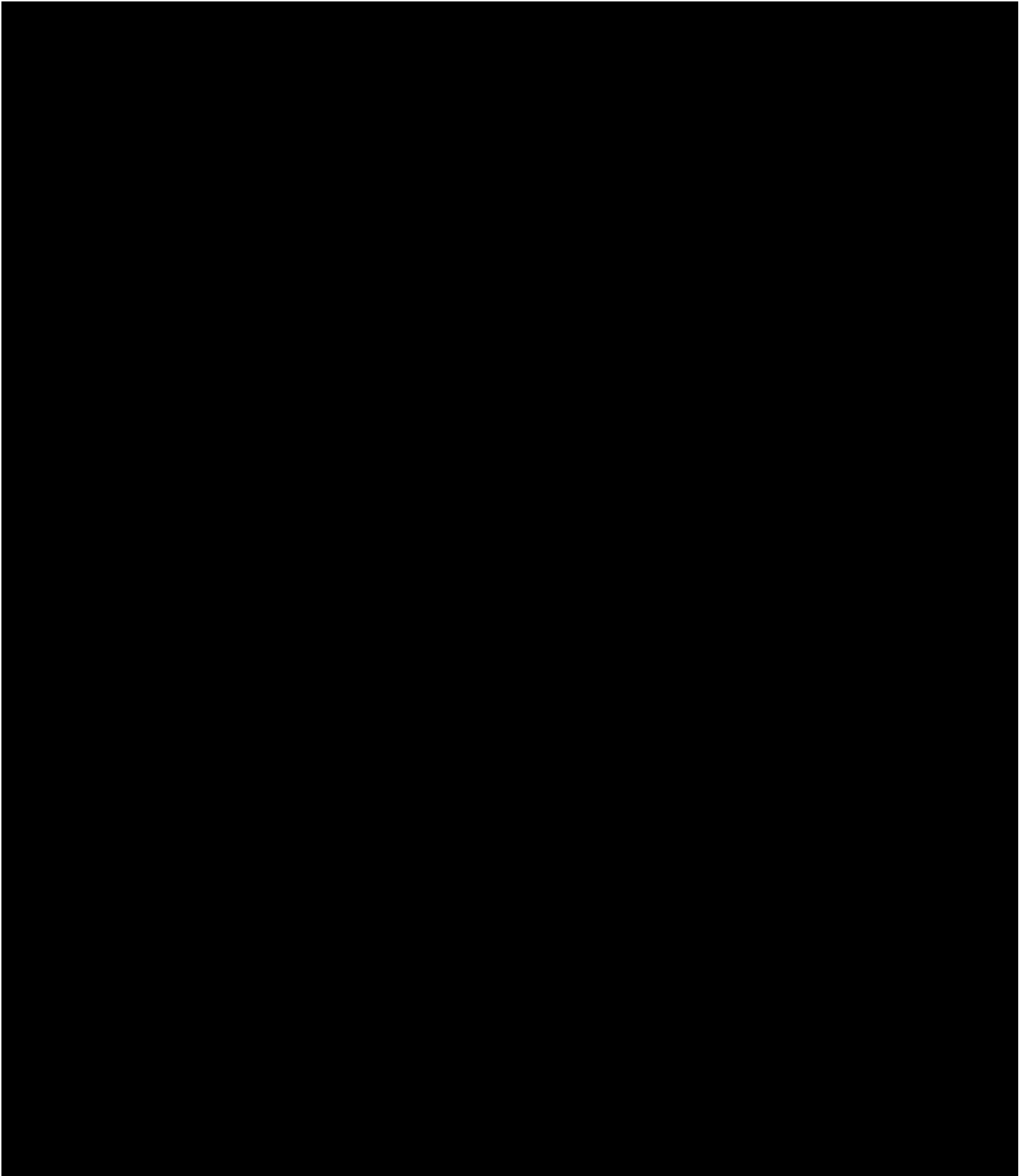
KURIN, INC.,

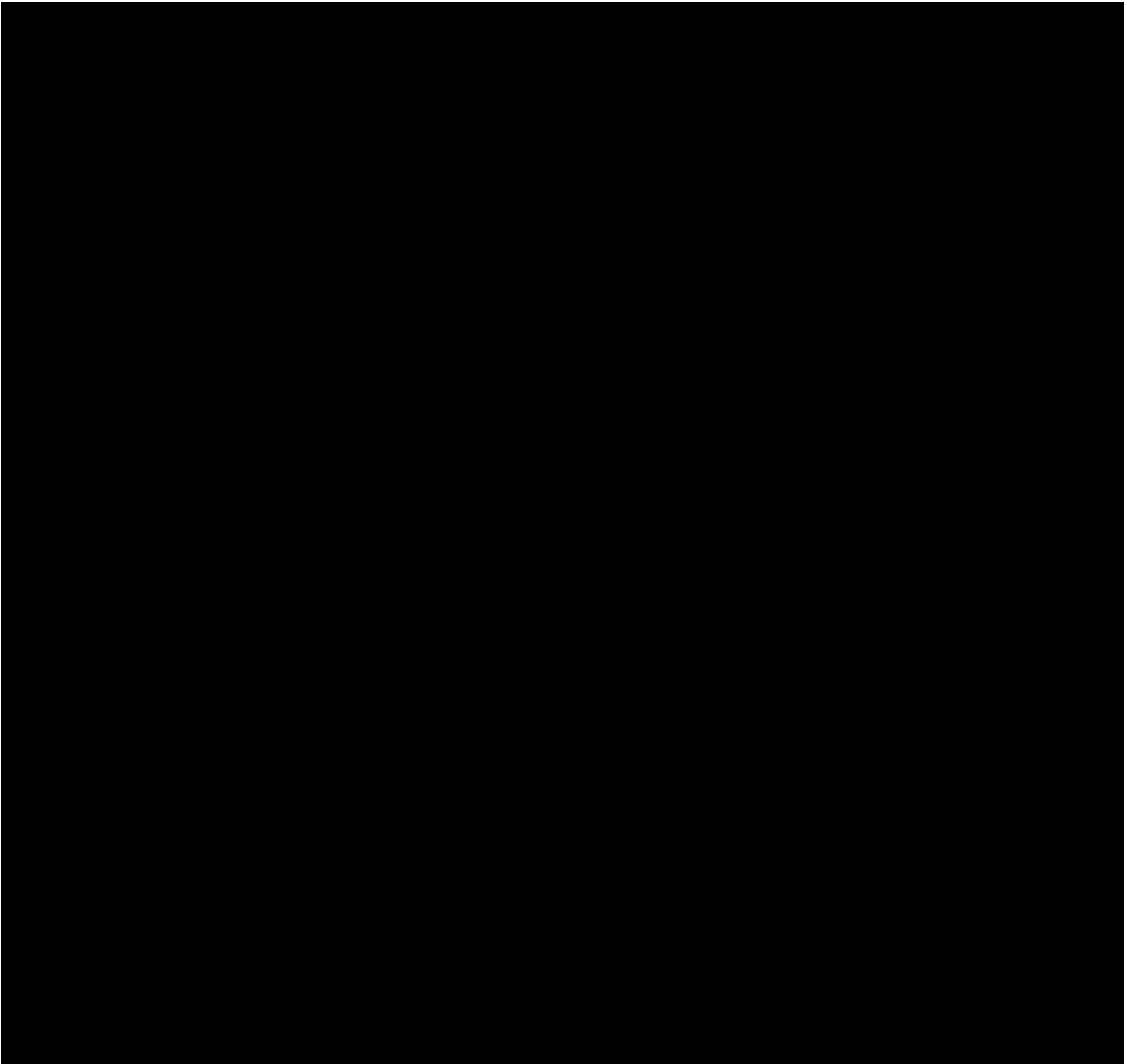
Defendant.

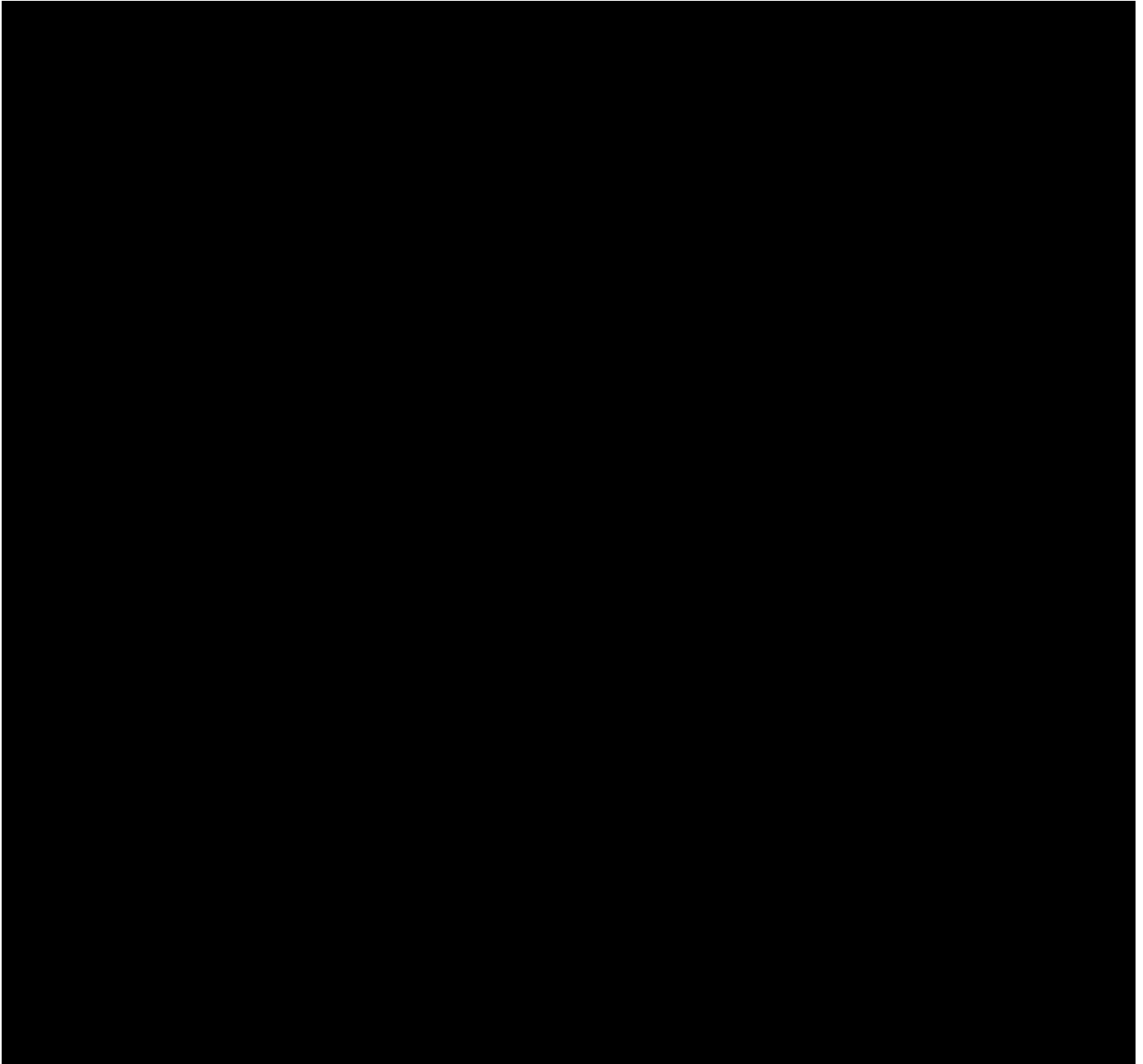
C.A. No. 19-00097-CFC

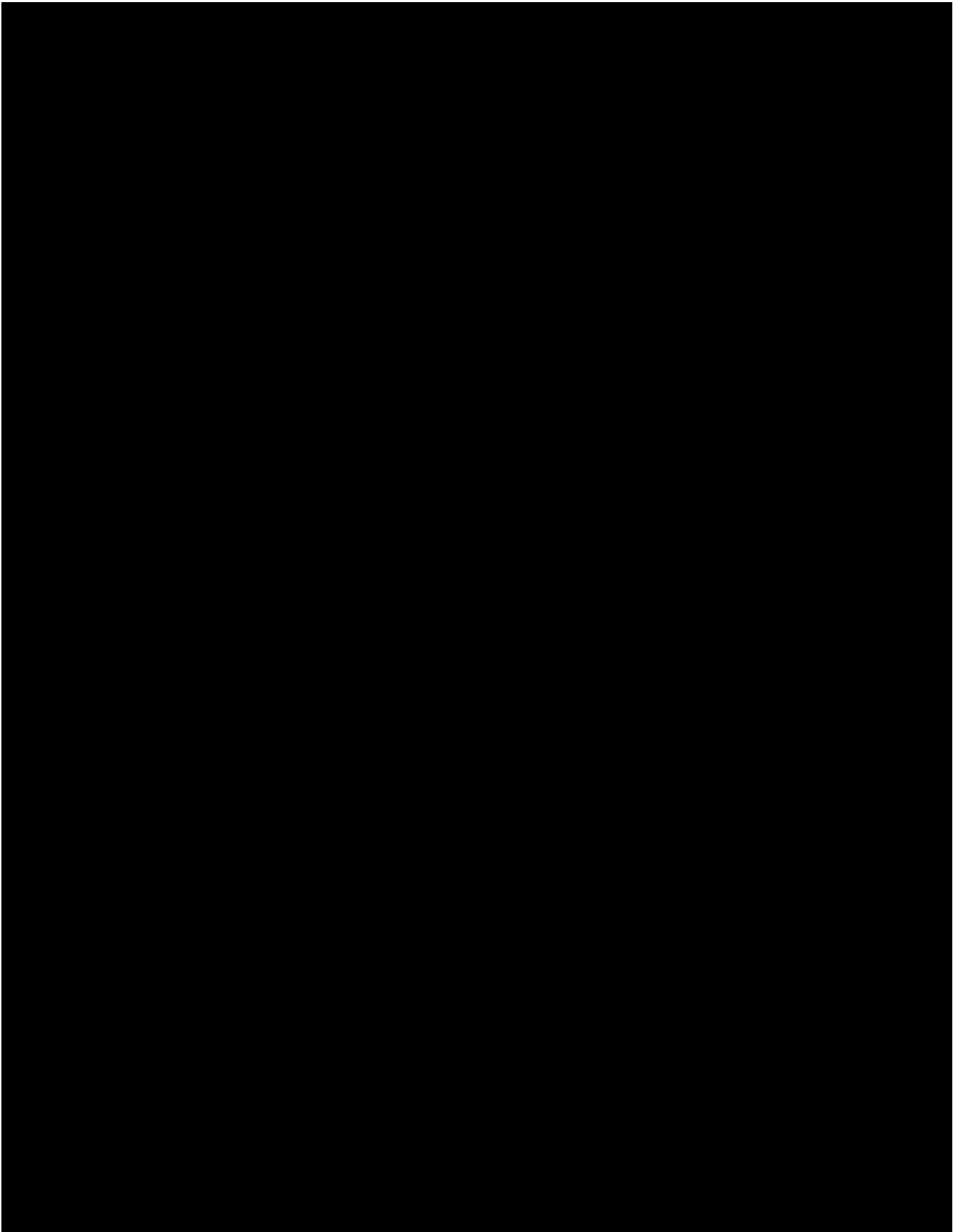
CONFIDENTIAL

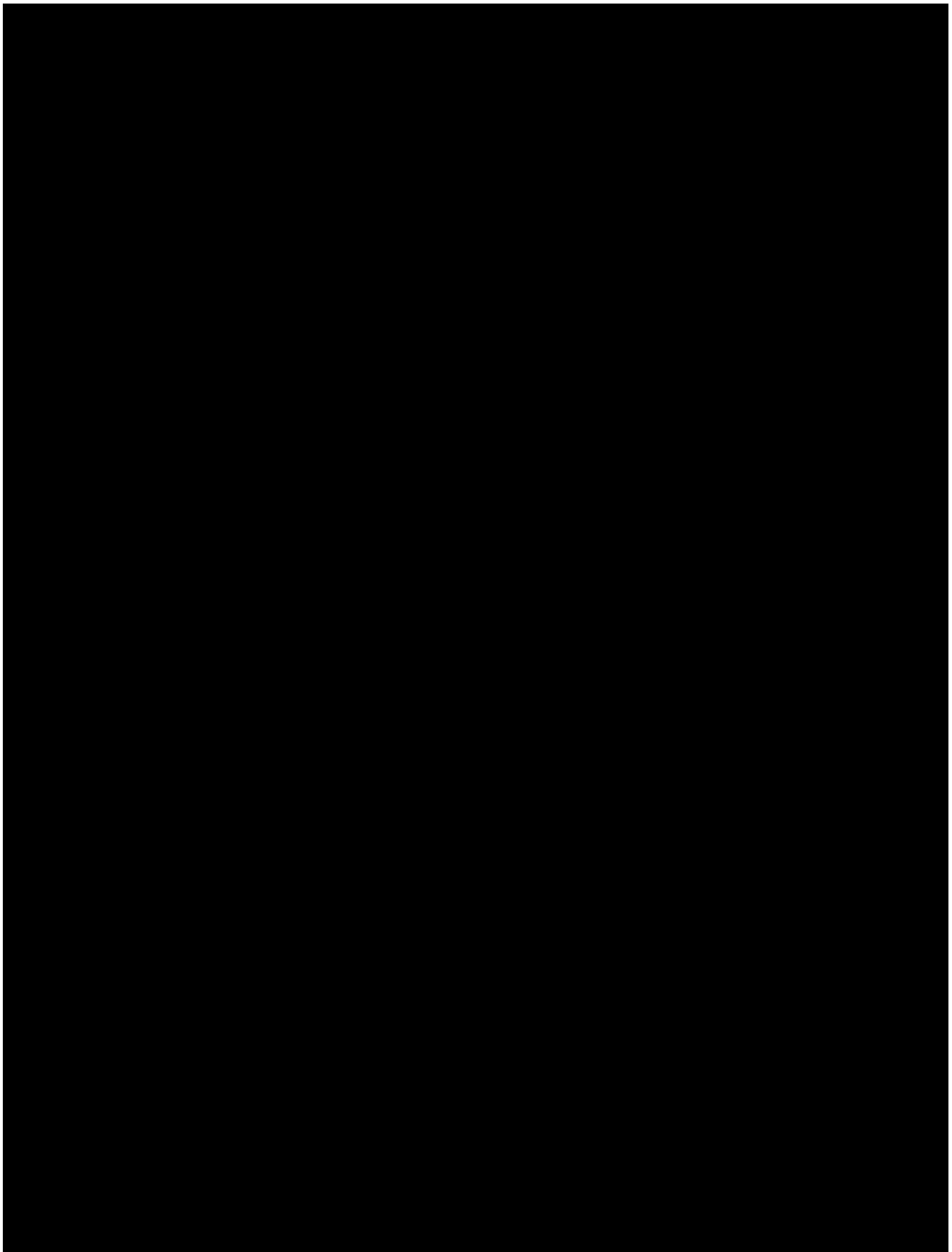
OPENING EXPERT REPORT OF DR. JUAN G. SANTIAGO
REGARDING INFRINGEMENT OF U.S. PATENT NOS. 9,855,001
AND 10,039,483

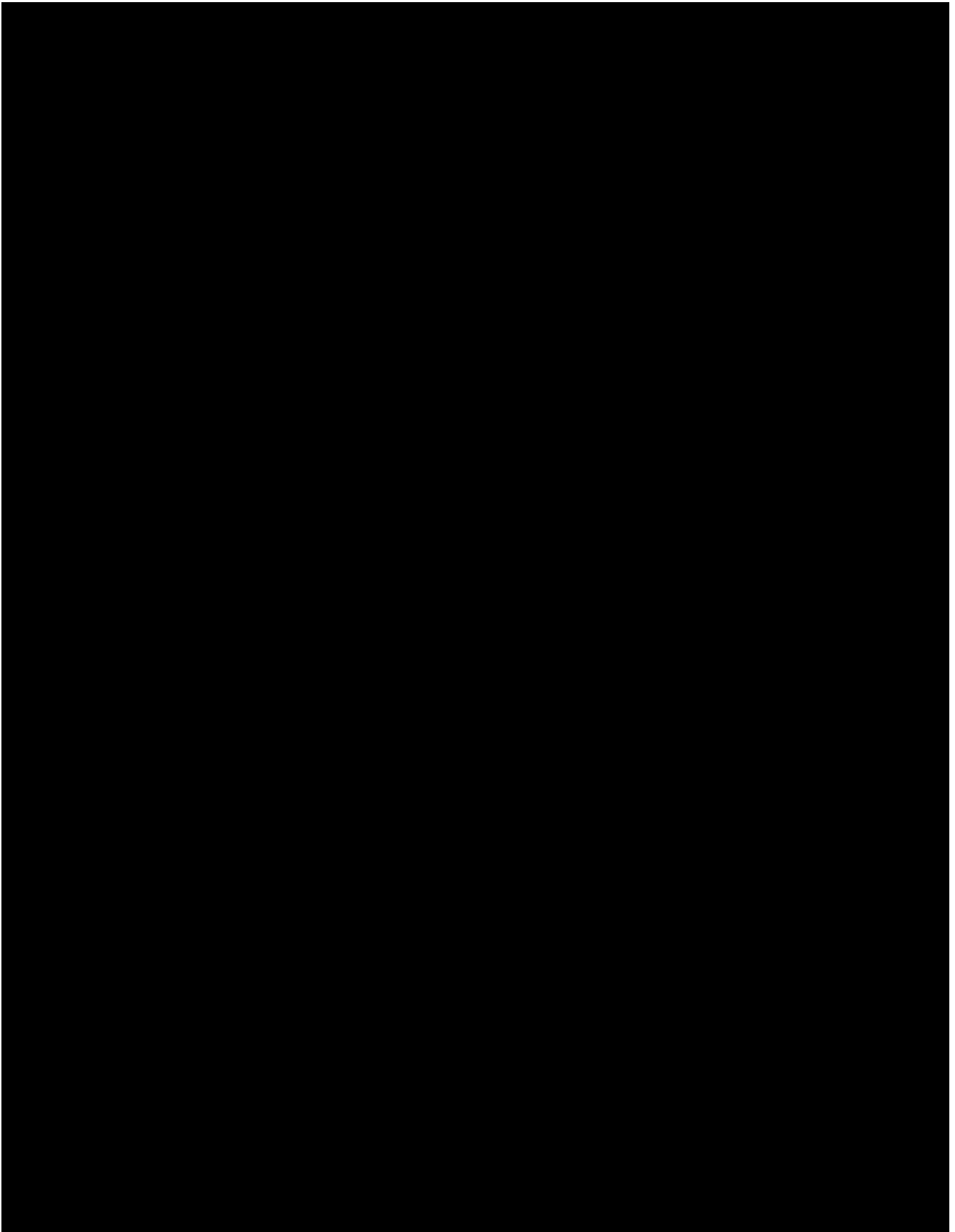


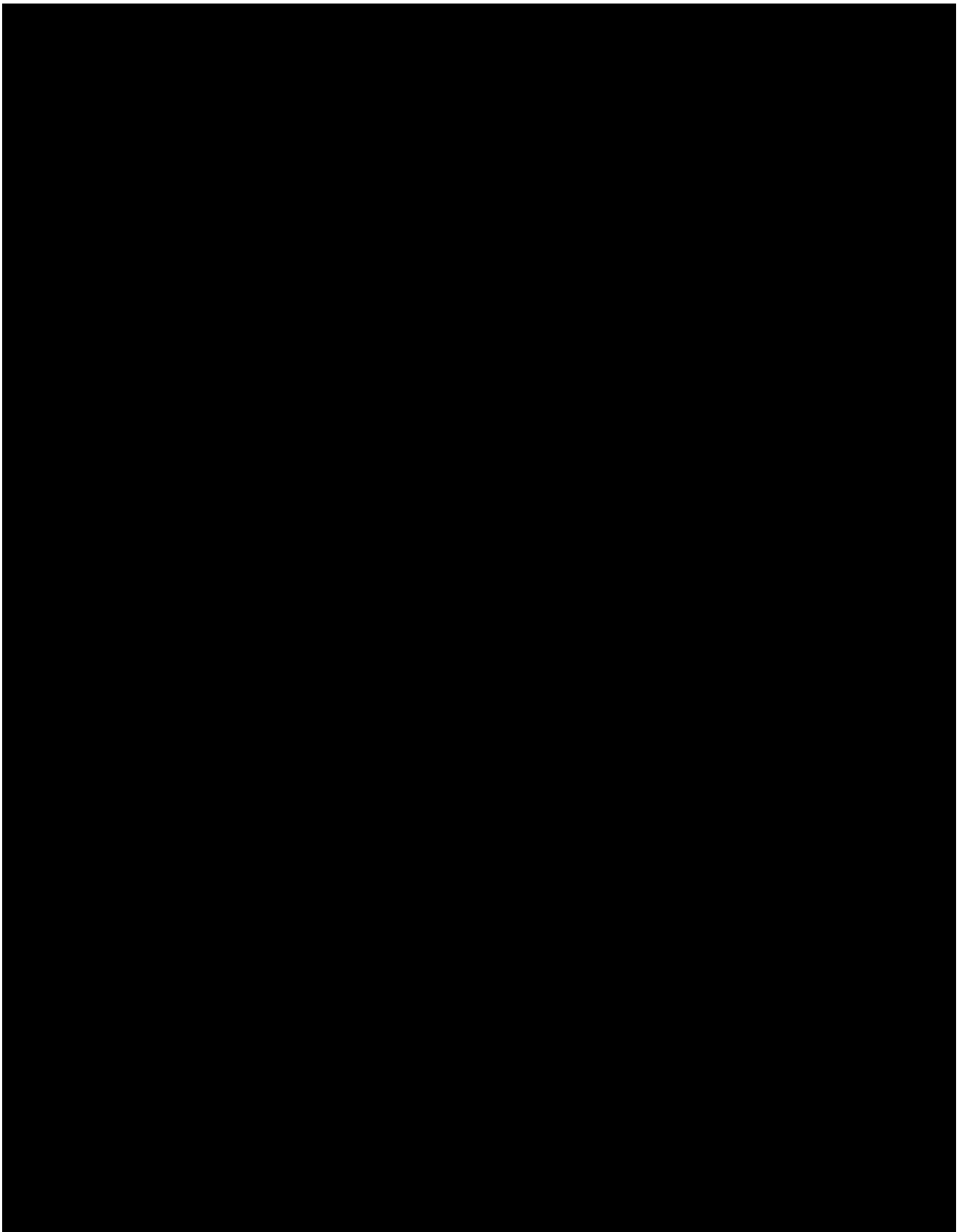


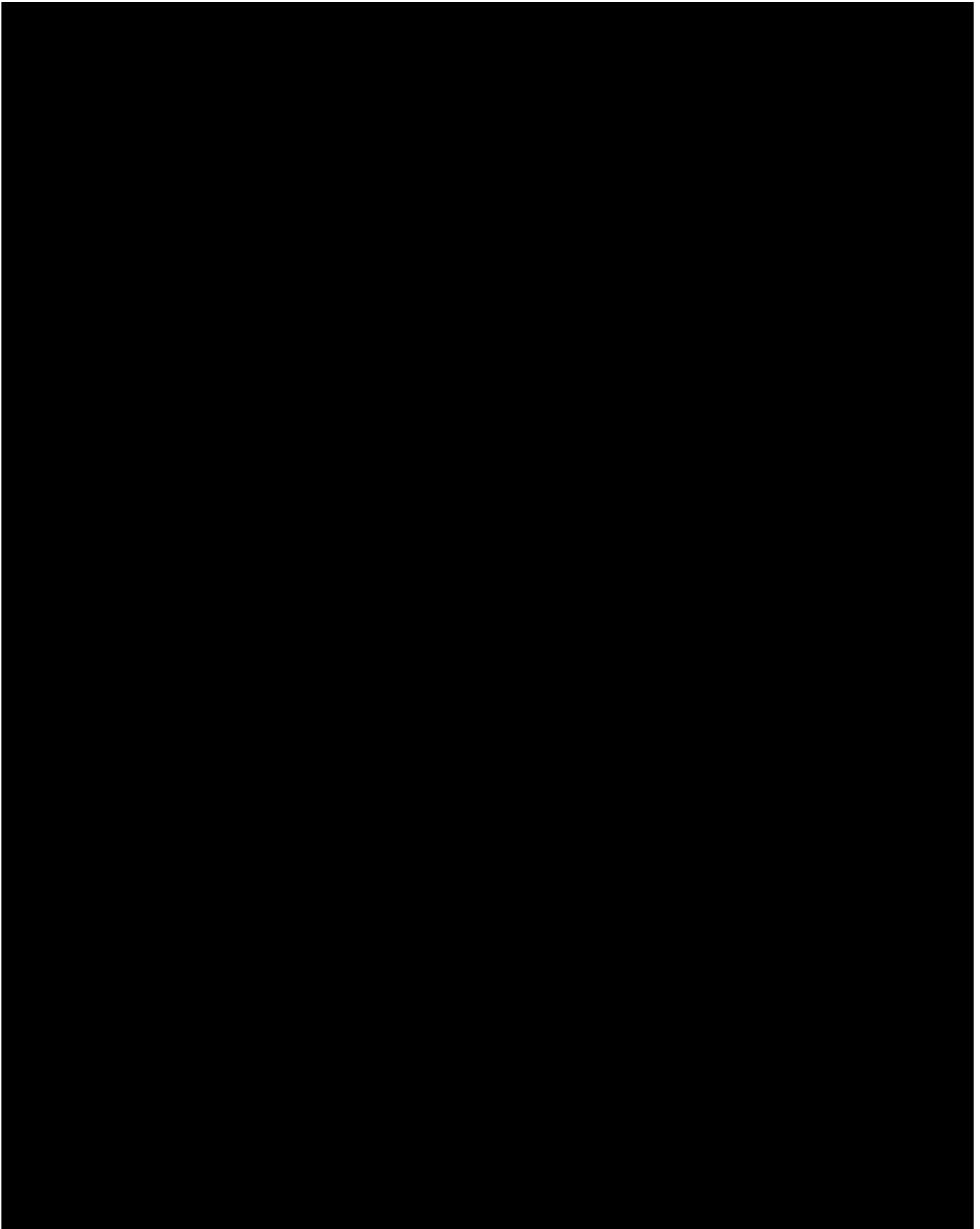


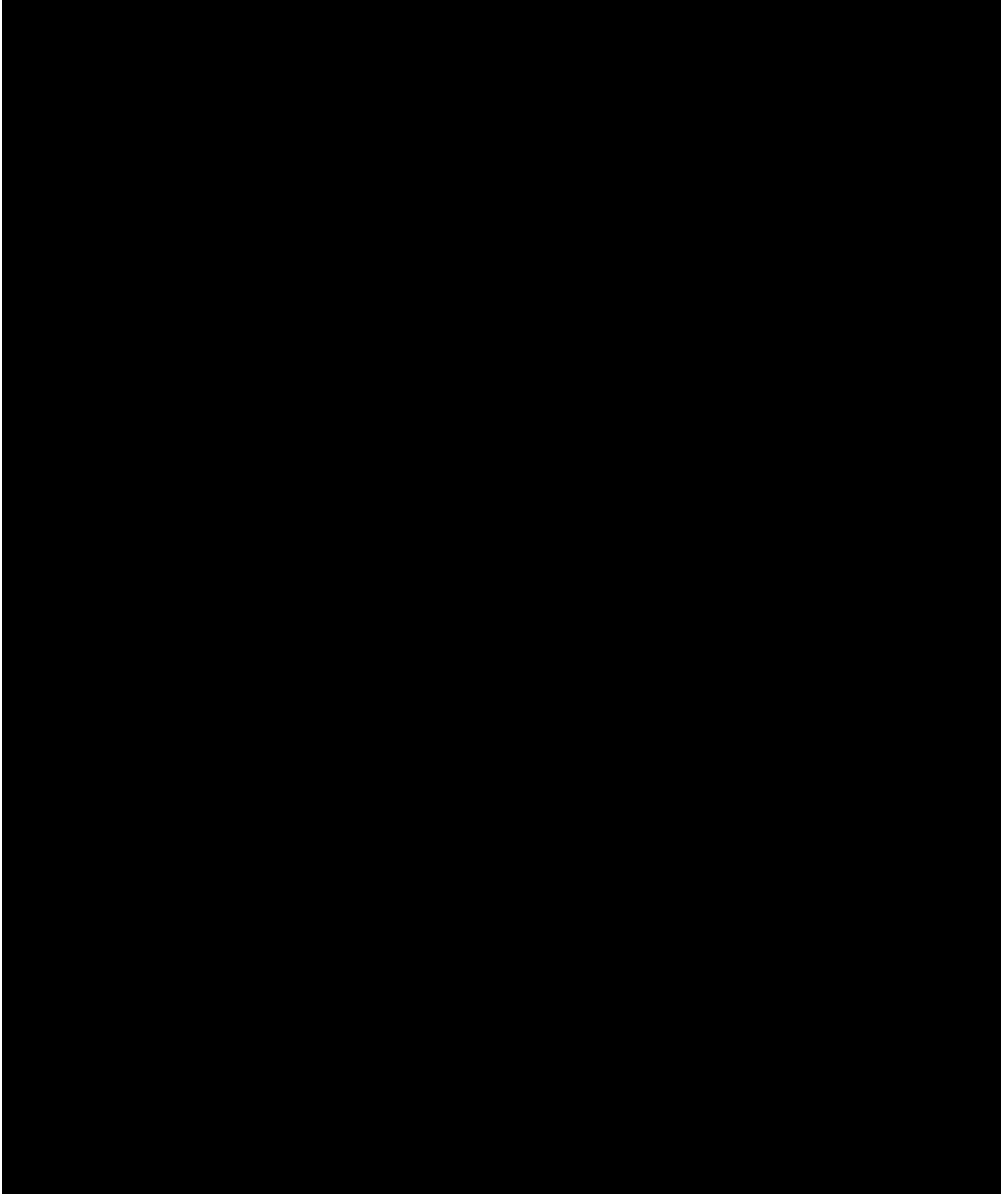


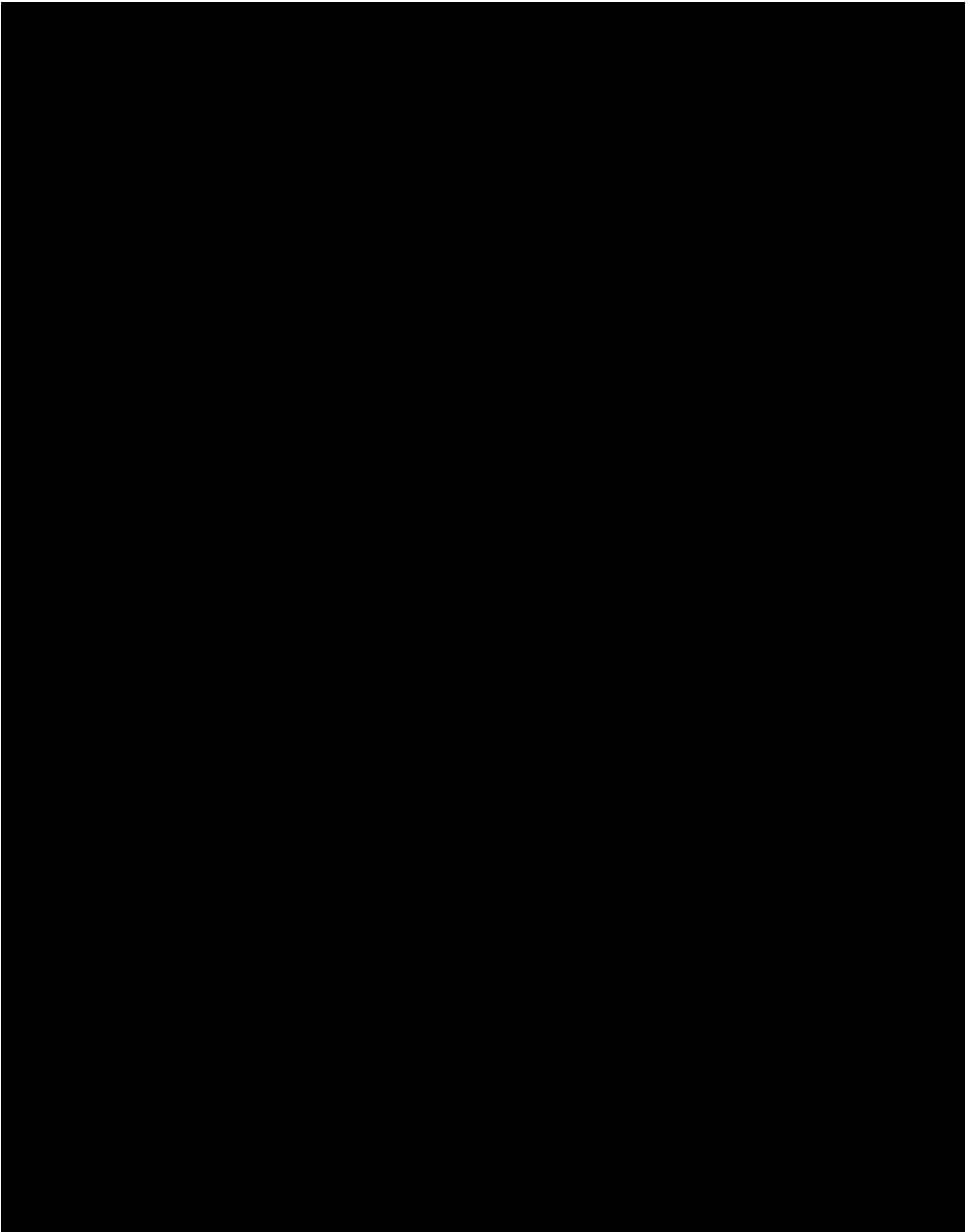


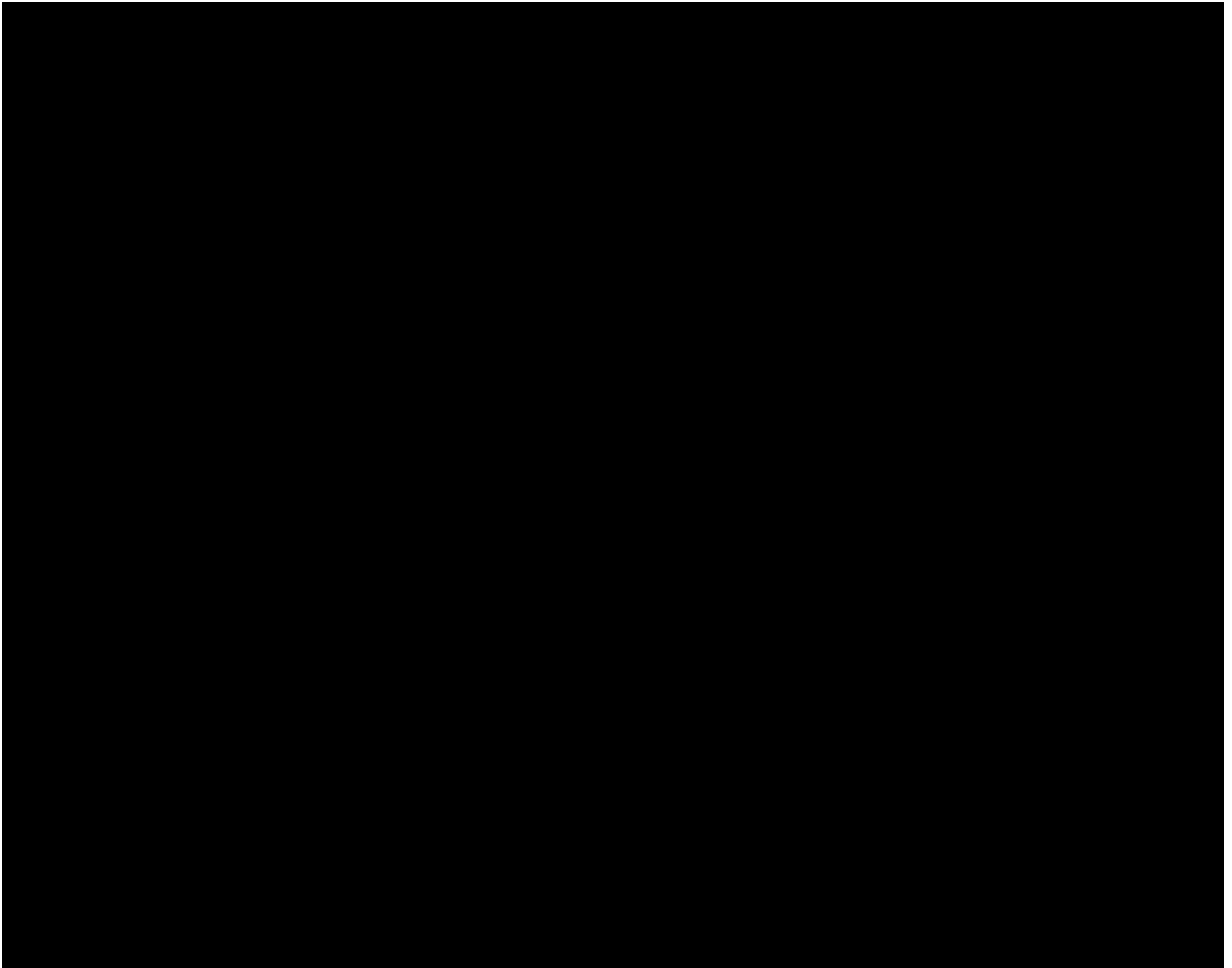


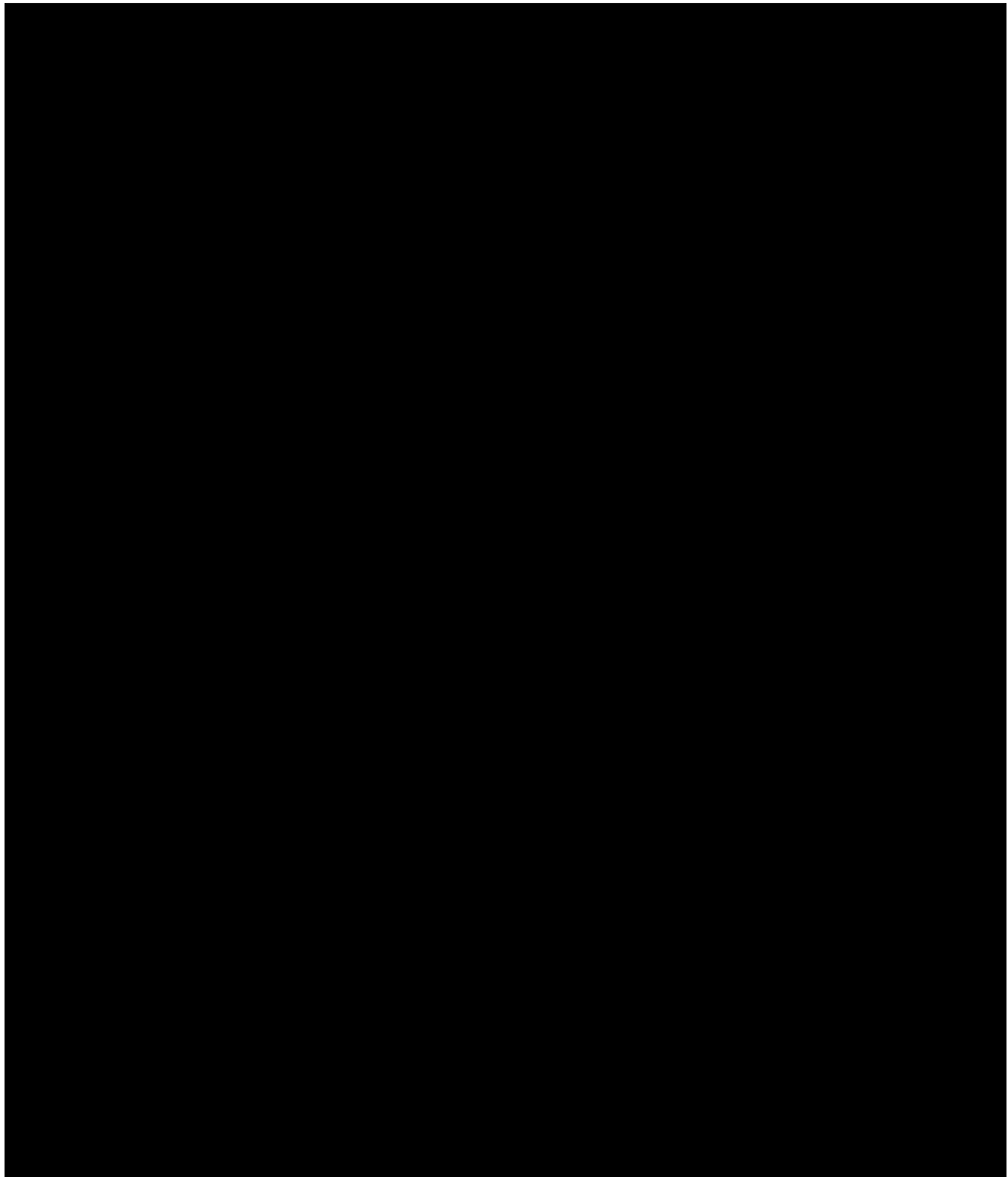


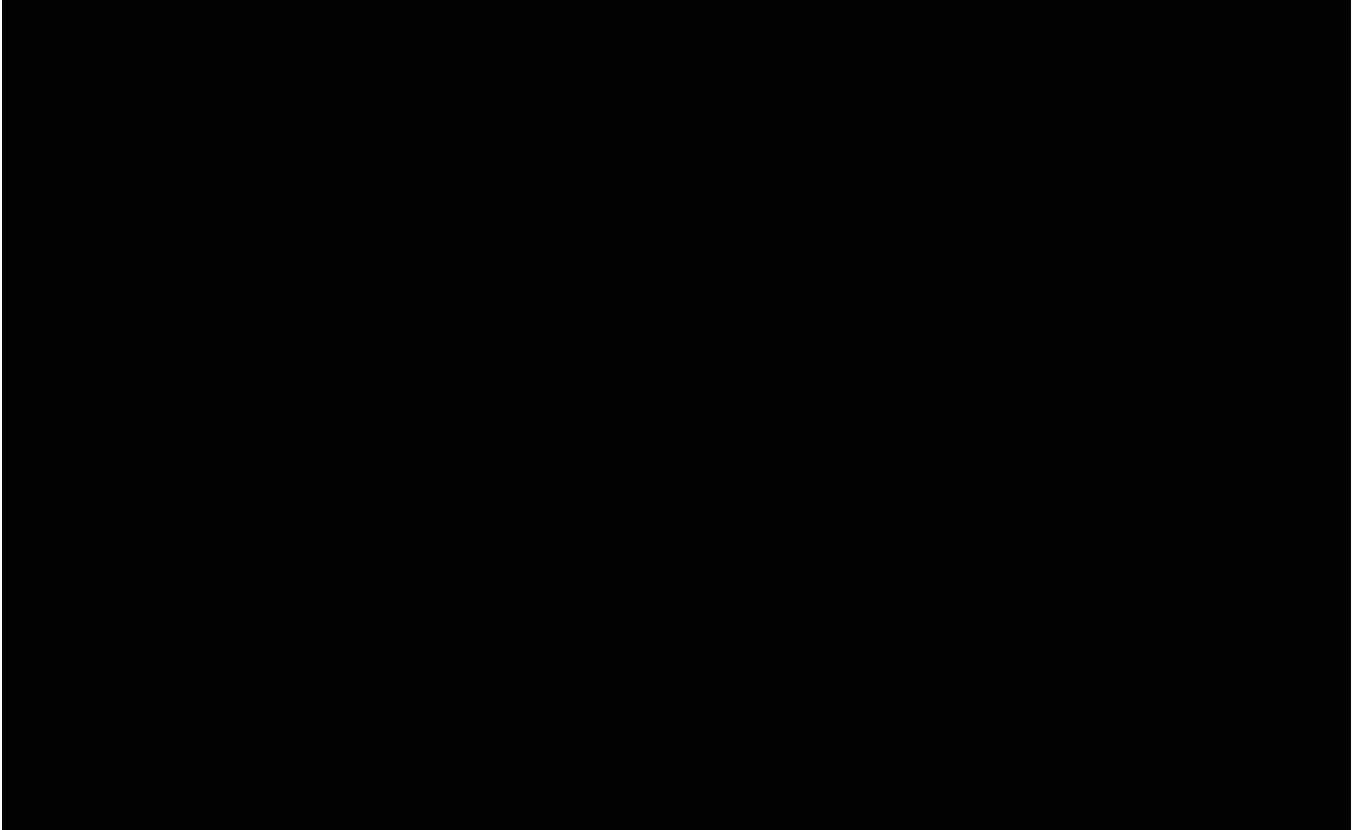


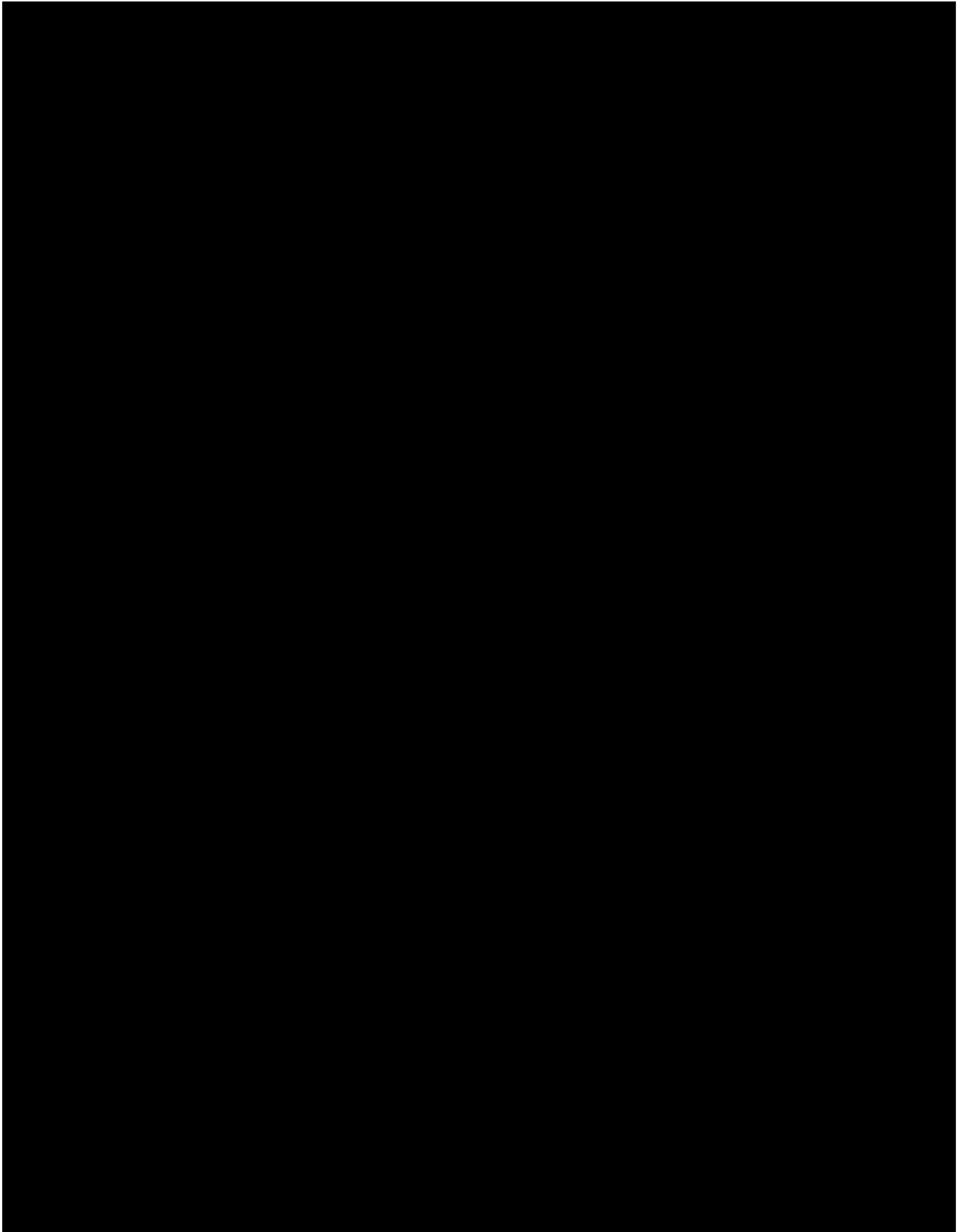












A series of eight horizontal black bars of varying lengths, representing redacted text. The bars are stacked vertically, with the longest bar in the middle and the shortest at the top and bottom.

A series of horizontal black bars of varying lengths, representing redacted text. The bars are stacked vertically, with some having small gaps between them. The lengths vary significantly, with some bars spanning most of the width of the page and others being much shorter.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

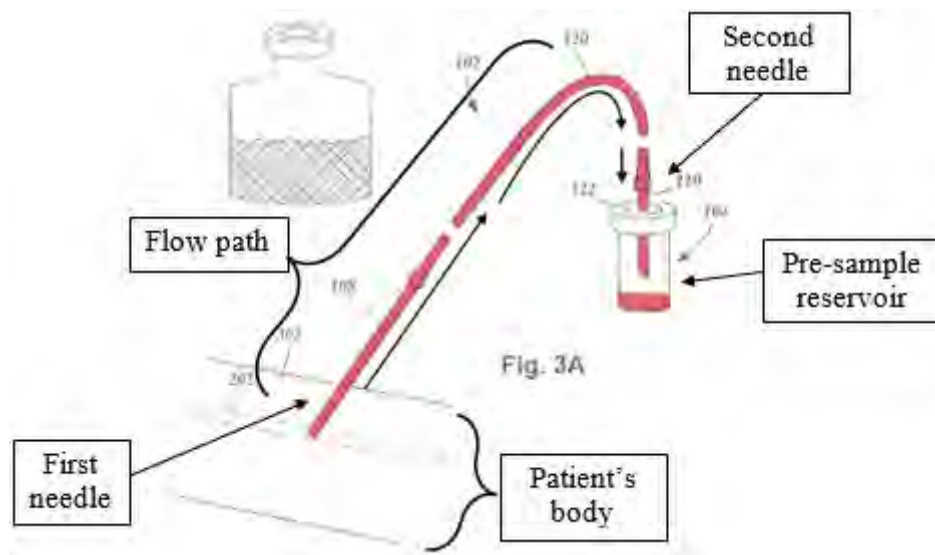
[REDACTED]

and that such “[f]alse positive results from microbial tests can cause a patient to be unnecessarily subjected to one or more anti-microbial therapies...which may cause anguish and inconvenience to the patient, as well as produce an unnecessary burden and expense to the health care system.” ’001 patent at 1:63-2:5.⁴ To tackle this problem, Dr. Patton invented various systems and methods to reduce contamination. Among his core inventive concepts were “divert[ing] the flow of bodily fluids from a patient” such that “an initial volume of withdrawn bodily fluid is placed in one or more pre-sample reservoirs and is not used for the incubation in culture media.” *Id.* at 7:49-50, Abstract. These concepts permeate each of the embodiments described and claimed in the ’001 patent.

121. For example, as shown in Figures 3A/3B, one way of diverting an initial blood volume is through use of a single blood flow path. *Id.* at 5:20-47. Initially the blood (and the majority of the foreign contaminants) flow through the

⁴ Along with dermally residing microbes, IV lines may also contain contaminants. In a study “comparing bacterial colonization of BCs [blood cultures] drawn either through venipuncture routes or from intravascular catheters,” some “studies reported higher BCC [blood culture contamination] rates ranging for samples drawn via catheters (range, 3.4%-13%) than from blood obtained by venipuncture (range, 1.2%-7.3%).” Robert Garcia et al. “Multidisciplinary team review of best practices for collection and handling of blood cultures to determine effective interventions for increasing the yield of true-positive bacteremias, reducing contamination, and eliminating false-positive central line-associated bloodstream infections” [MAG-DEL0012937] at 1225. Therefore, diverting the initial volume of blood from an IV tap is also important when using a peripheral IV configuration rather than venipuncture.

single flow path into a “pre-sample reservoir.” *Id.* at 5:20-23, 5:29-41. The flow path consists of a “first needle” that is inserted into a fluid-containing portion of a body (such as a vein), *id.* at 5:2-9, a “second needle” that can be inserted into the pre-sample reservoir, *id.* at 5:20-23, and “sterile tubing” connecting the two needles, *id.* at 5:29-32. Through this flow path the blood travels into the pre-sample vessel, as shown in Figure 3A (annotations and color added):



122. When the pre-sample reservoir fills, it can be removed and replaced with a “sample vessel” (e.g., a container for collecting and testing blood). *Id.* at 6:16-18. A subsequent volume of blood from the patient travels through the same flow path but into the sample vessel, as shown in Figure 3B (annotations added):

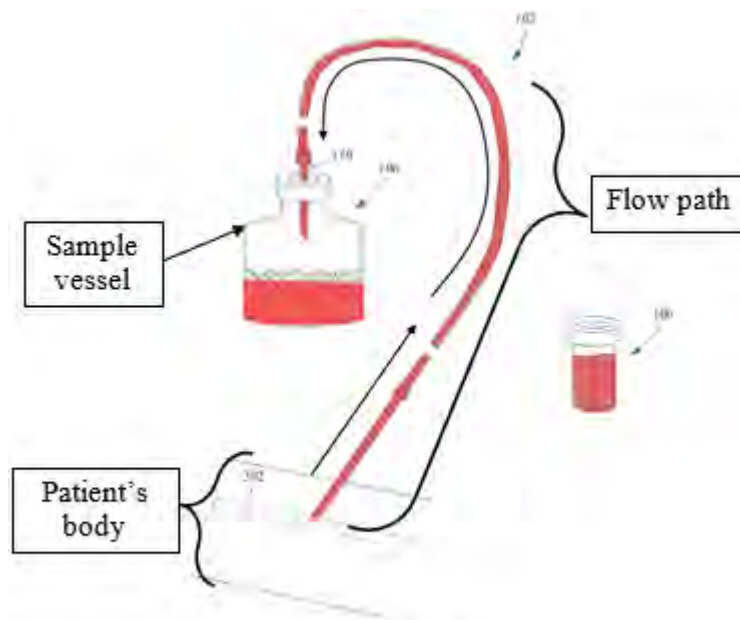
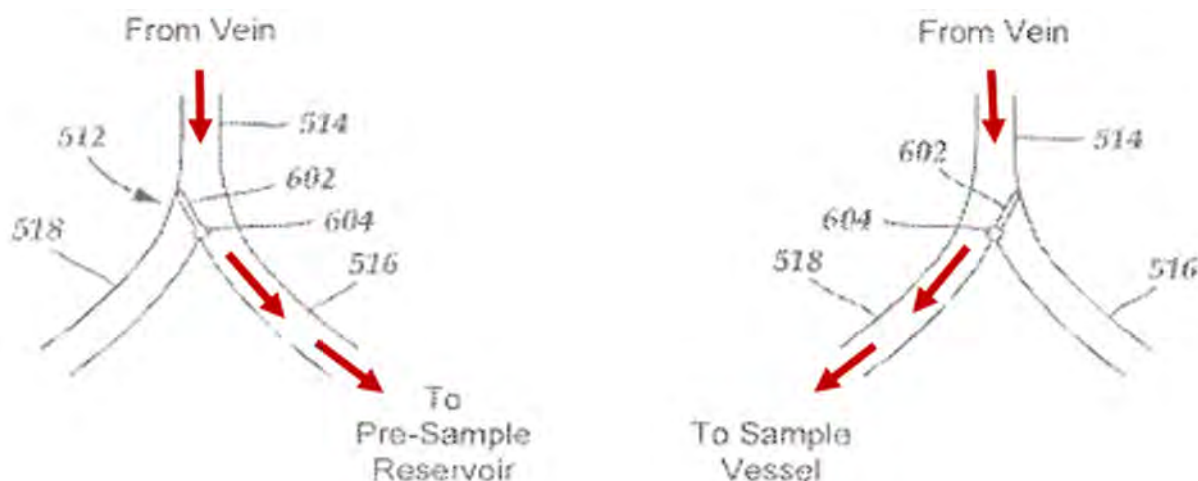


Fig. 3B

The pre-sample reservoir, with its potentially contaminated blood, is kept apart from the sample vessel, reducing the likelihood that testing the blood in the sample vessel will lead to false positives. *Id.* at 5:48-50, 5:56-62.

123. Another way of diverting an initial blood volume, as shown in Figures 6A/6B, utilizes a flow path from the patient that branches into two separate paths, one leading to the pre-sample reservoir and the other leading to the sample vessel:



Id. at Figs. 6A, 6B (color added).

124. The patent explains that “[m]any different types of diversion mechanisms can be used to divert the flow of bodily fluids from a patient,” *id.* at 7:49-50, and that the diversion can take place either “manually or automatically,” *id.* at 8:23-26. In the example illustrated in Figures 6A/6B, the system includes a switchable valve (602) to allow blood to flow either toward the pre-sample reservoir or toward the sample vessel. *Id.* at 7:50-8:6.

B. Prosecution History

125. The '001 patent application was filed on March 13, 2017. The patent application originally included 20 claims. '001 patent file history, 2017-03-13 Claims. A preliminary amendment was filed on the same day, March 13, 2017, canceling the original 20 claims and adding 30 new claims. *Id.*, 2017-03-13 Preliminary Amendment & Claims. The Applicant responded to a restriction requirement on April 11, 2017, where the Applicant noted that all pending claims read on the elected species. *Id.*, 2017-04-11 Applicant Remarks.

126. After a non-final rejection, I understand that the Applicant added the requirement of obtaining a bodily fluid sample from a patient “with reduced contamination” and additional requirements to the “diverter” configuration. *Id.*, 2017-07-14 Claims. On September 5, 2017, I understand the Examiner issued a

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

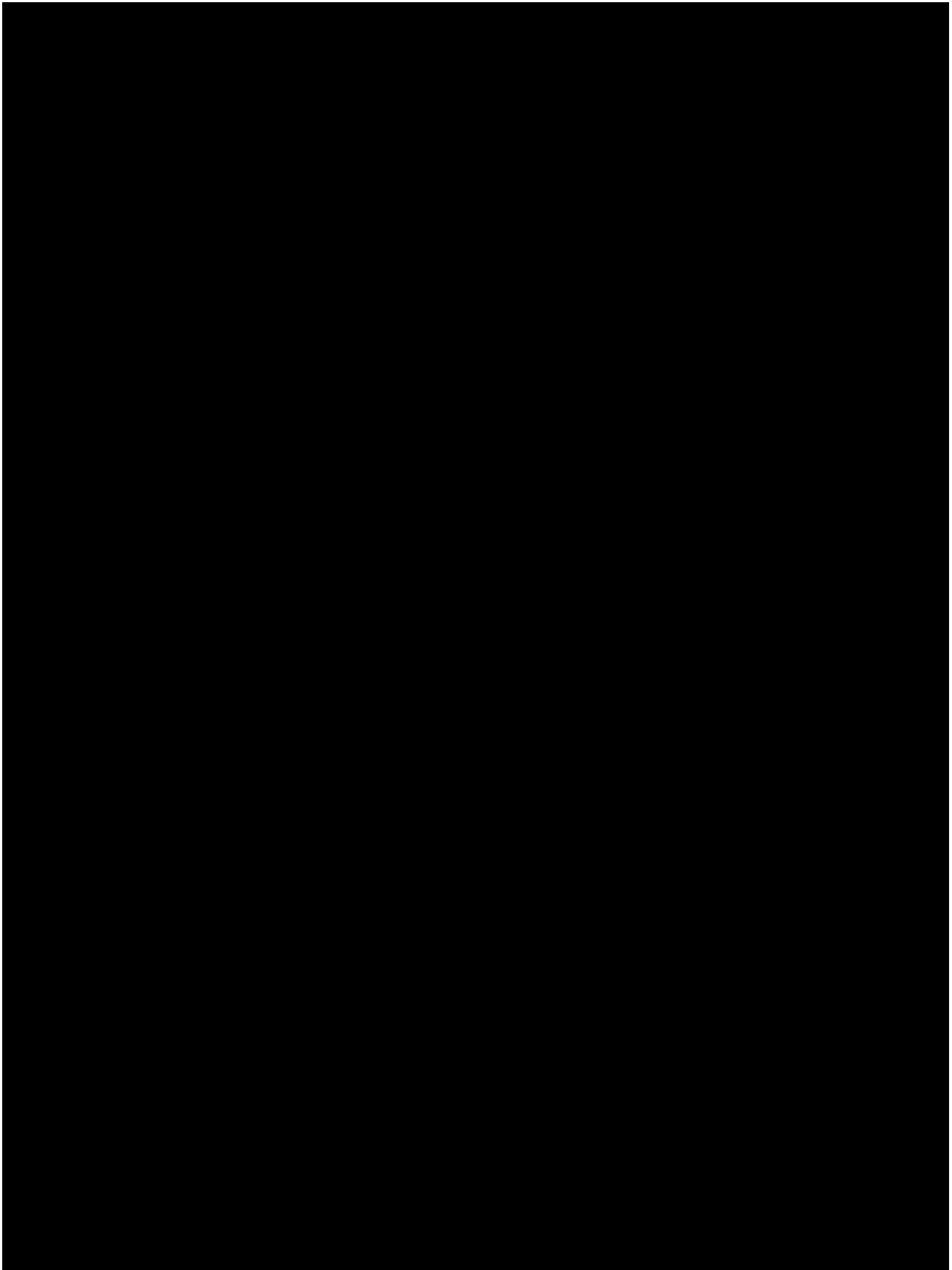
[REDACTED]

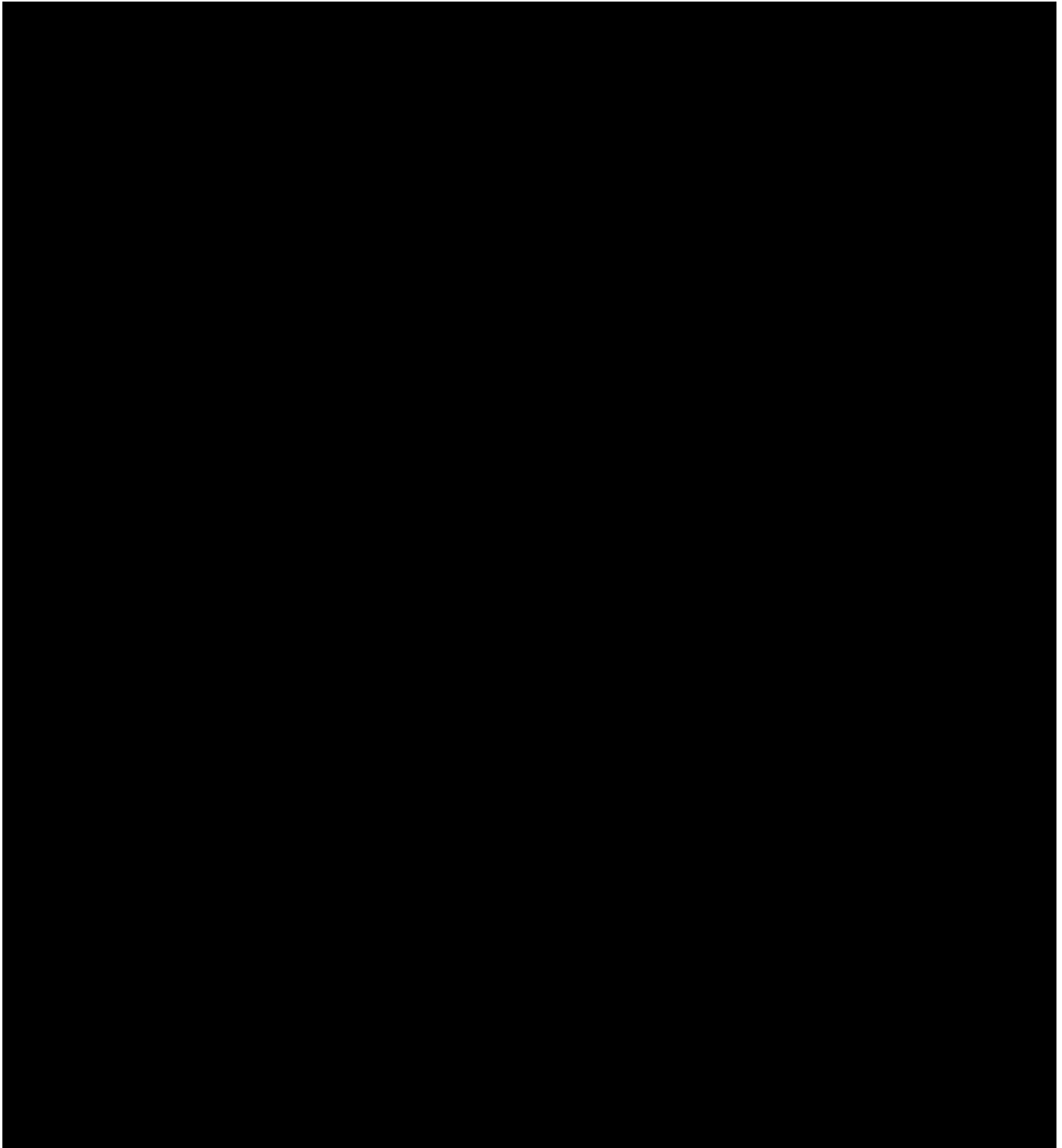
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





4 Q. And you said that one of the reasons
5 you wanted them was you wanted to see what the
6 product is supposed to do.

7 What was your understanding, once
8 you educated yourself, of what the Kurin Lock is
9 supposed to do?

10 MR. HANGARTNER: Objection. You can
11 go ahead and answer.

12 THE WITNESS: So, the device is
13 intended for blood collection. The goal is
14 to reduce contamination in blood collection.

15 And it achieves that by, my
16 understanding is it is sort of a waste tube
17 process.

18 It collects the first volume of
19 blood that may have contaminants in one
20 portion, and then allows the rest of the
21 collection to go into the collection vial, to
22 reduce potential contaminations in a vial.

Page 41

1 BY MS. BROOKS:

2 Q. And I'm sorry, you cut out again on
3 that last part. You said reduce contaminations
4 in?

5 A. In the collected sample.

2020-08-20 Nason Dep. Tr. at 40:4-41:5.

b. **1[a]: a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and**

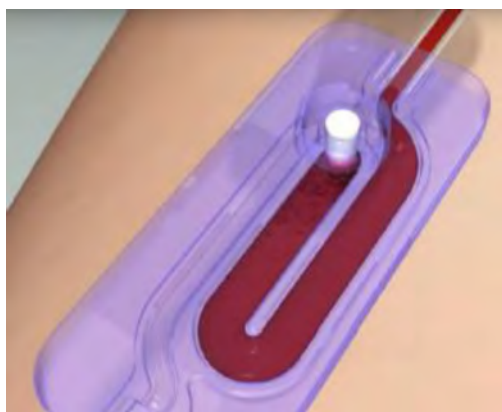
133. The Court construed the term “initial volume” (D.I. 75 at 2):

“initial volume”	“the initial portion of blood removed from the patient and sequestered”
#001 Patent: claims 1, 4, 21-23	
#483 Patent: claims 1, 8, 9, 24	
#139 Patent: claims 1, 13, 19, 23, 27	

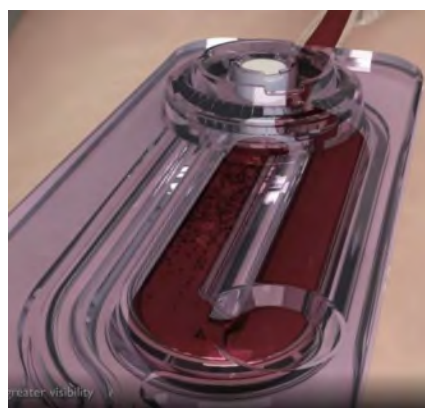
134. Each of the Accused Products includes a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient. *See, e.g.,*

MAG-DEL0000838 (Kurin Video 07/09/2019) (“Kurin is a device designed to contain the initial volume of blood from the venipuncture site so that resident contaminants within the skin are not transferred into the blood culture sample.”); MAG-DEL0826802 (Kurin Video 01/2021) (“The Kurin Lock[®] with Flash Technology sidelines the initial flash of blood from an accessed vein to reduce skin contaminants that enter into the blood culture sample.”)

MAG-DEL0000838 at 0:44:



MAG-DEL0826802 at 0:22:



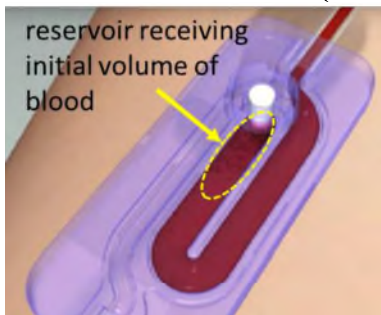
KUR-MAG-DE001632 (IFU_Kurin Blood Culture Collection Set with Kurin Lock[™] Technology) (“The Kurin set is a sterile, single-use blood culture collection set. Kurin includes a winged needle with flexible tubing and an attached blood culture bottle holder intended for venipuncture to obtain blood culture samples. The Kurin Lock blood capture device sequesters the initial draw of blood upon venipuncture.”);

KUR-MAG-DE002283 (IFU_Kurin PIV12 Blood Culture Collection Set with Kurin[®] Lock Technology) (“The Kurin PVV12 series of Kurin sets are sterile, single-use blood culture collection sets that include the Kurin Lock, flexible tubing, an attached blood culture bottle holder, and a male luer intended for direct connection to a freshly placed peripheral IV (PIV) catheter to obtain blood culture samples. The Kurin Lock sequesters the initial draw of blood upon first access to the peripheral catheter.”)

135. The initial volume of blood does not have to be the entire volume of blood contained in the U-shaped diversion chamber. In my opinion, the initial volume of blood is the volume of blood that is actually sequestered in the U-shaped diversion chamber. As shown in the testing videos, a small portion of blood near the junction may (and is expected to) escape the region bounded by the U-shaped diversion chamber. However, the testing videos show that there is a large portion of blood that remains sequestered in the U-shaped diversion chamber. The latter is the initial volume of blood from the patient described by the patents.

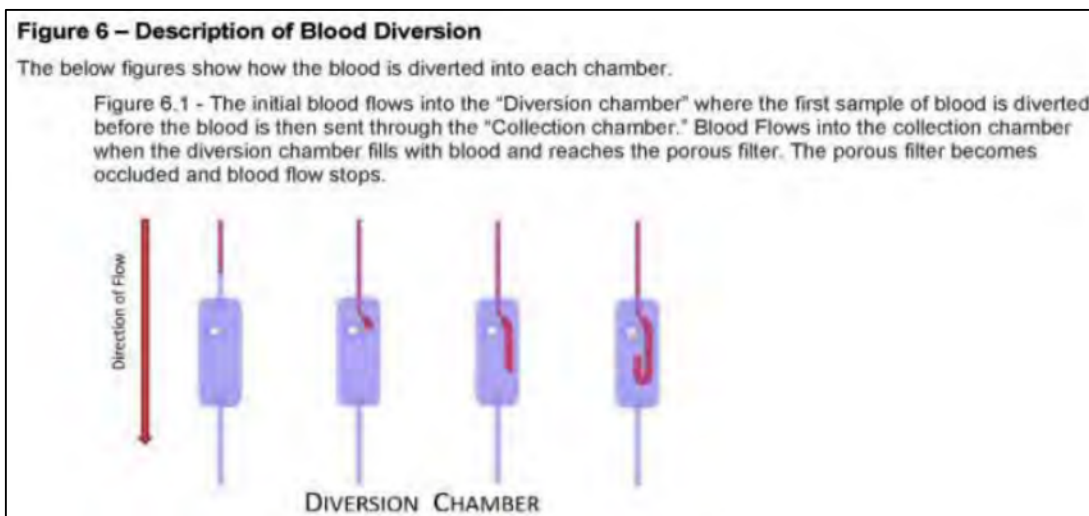
136. The U-shaped diversion chamber includes a reservoir that receives the initial volume of blood from the patient:

MAG-DEL0000838 (Kurin Video 07/09/2019) (annotated):



See also MAG-DEL0826802 (Kurin Video 01/2021)

KUR-MAG-DE000147 (Description of Blood Diversion):



KUR-MAG-DE424575 (How Kurin Works):

6. Blood from the vein flows into the kurin based on patient's pressure! The blood moves into the Kurin and displaces the air located in the kurin. The blood will reach the Kurin plug. When the blood reaches the plug, the plug is activated and the chamber is sealed off. There is also a mechanism in place to prevent the backflow of blood and to lock the contaminated blood into the chamber. In general, If the patient's pressure is normal, blood will flow quicker, then a patient with lower pressure.

KUR-MAG-DE450383 [REDACTED]

137. Bob Rogers admitted that the initial volume of blood is received in the reservoir of the U-shaped diversion chamber (also known as the side channel) of the Accused Products:

10 Q Well, so the side channel is where the
11 first initial volume of blood goes. Is that fair?
12 MR. HANGARTNER: Objection. Calls for a
13 legal conclusion.
14 THE WITNESS: If the nurse allows, if
15 they insert a needle into the patient and the
16 patient's blood pressure is sufficient, yes, the
17 first amount of blood will go into where there is
18 an air leak, and that's the side channel.

2020-08-18 Rogers Dep. Tr. at 404:10-18.

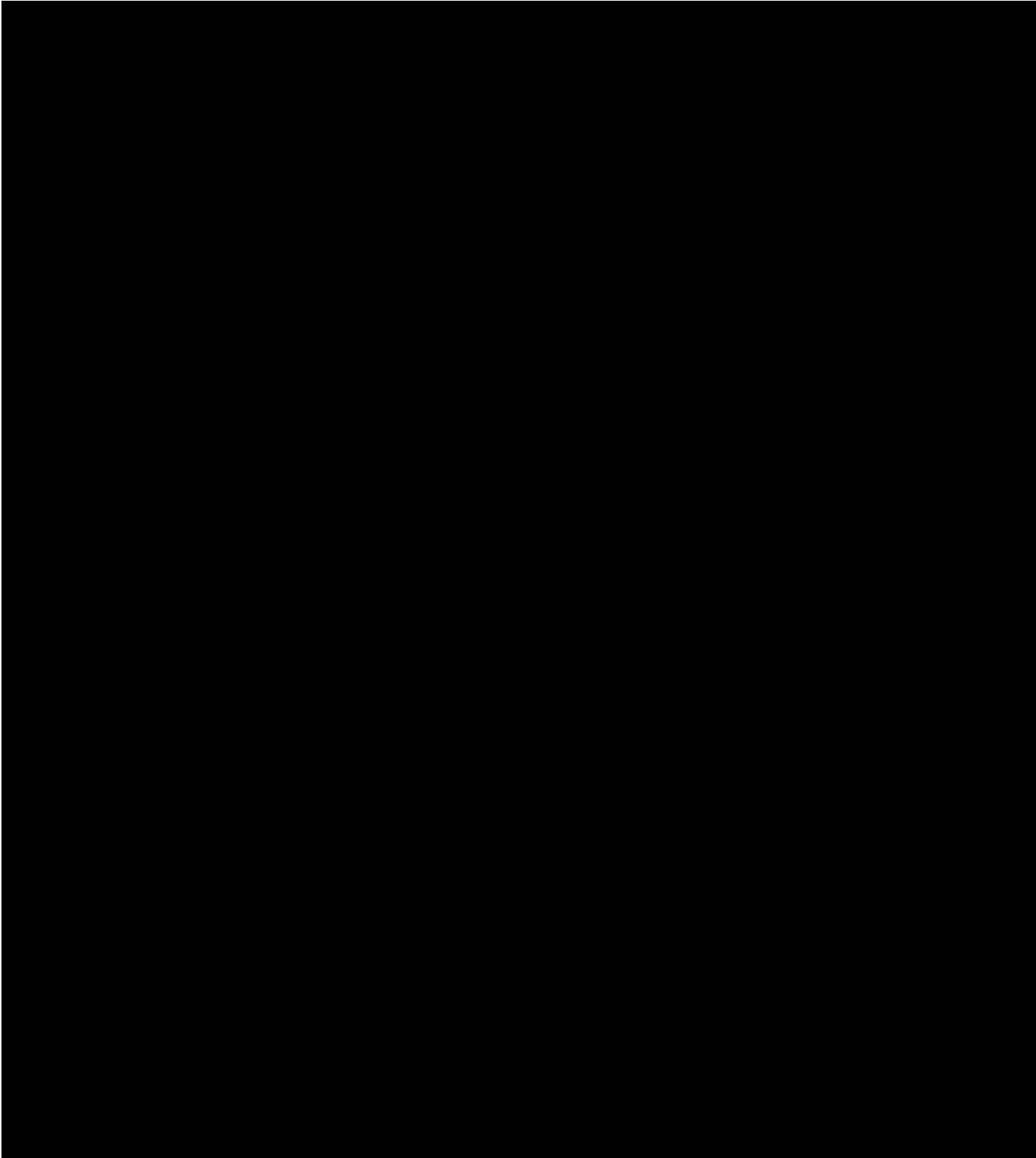
138. Kevin Nason admitted the same:

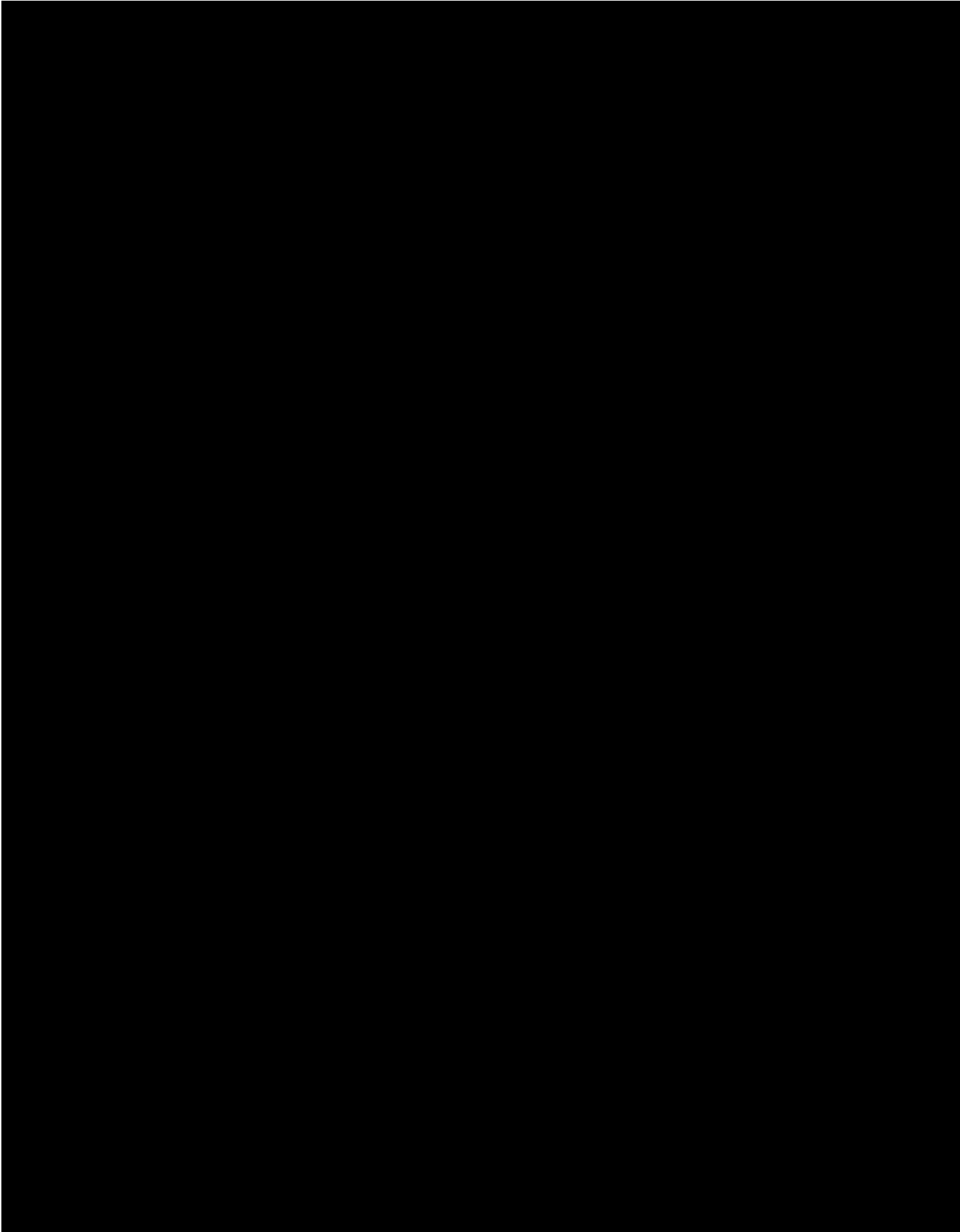
17 Q. And why is it important to try to
18 fill that side channel before the blood then
19 starts flowing down the sample path into the
20 collection chamber -- collection device?
21 MR. HANGARTNER: Objection.
22 THE WITNESS: Well, the function of
Page 59
1 that is to collect the initial volume of
2 blood in there that potentially has
3 contaminants.

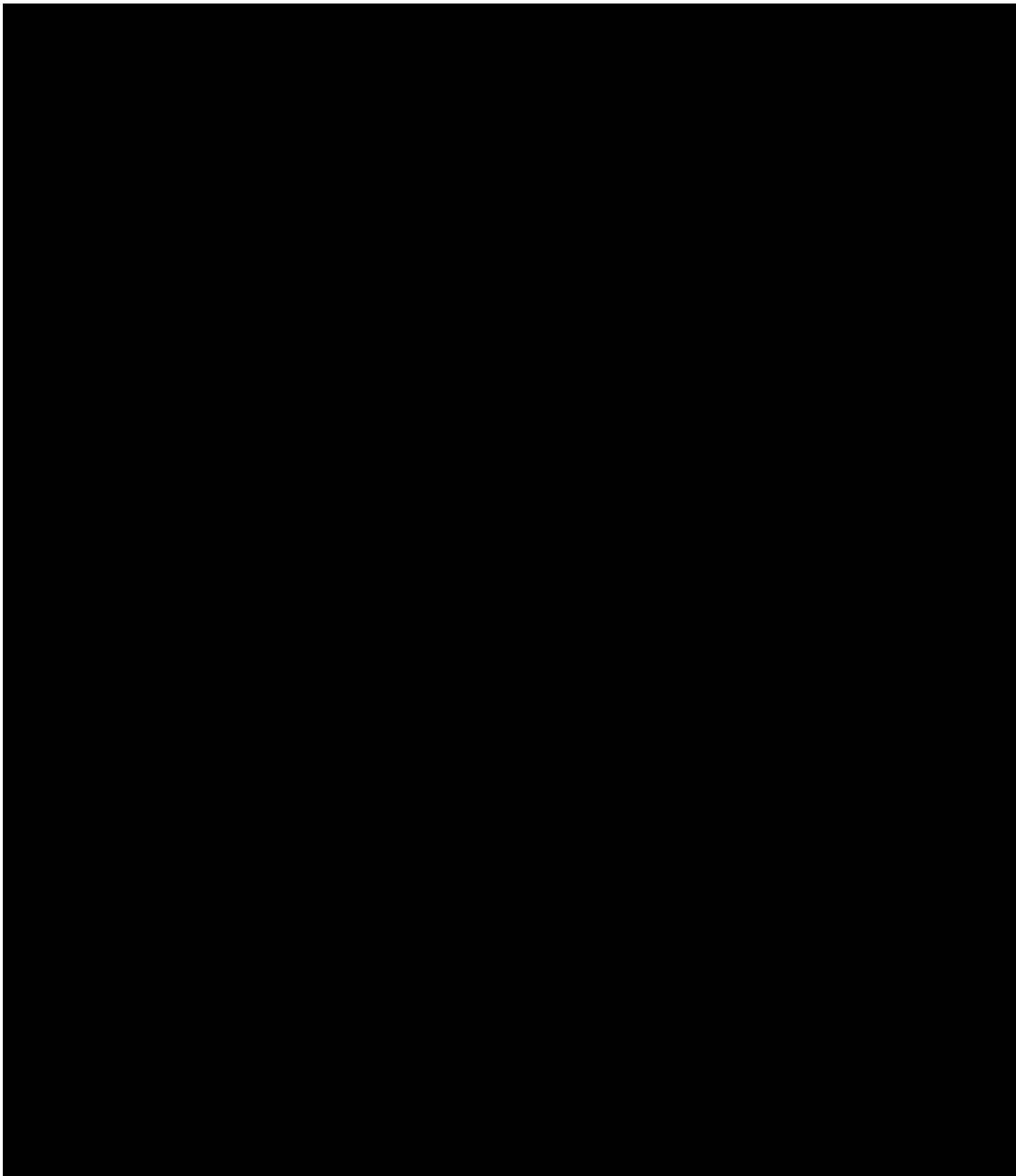
2020-08-20 Nason Dep. Tr. at 58:17-59:3.

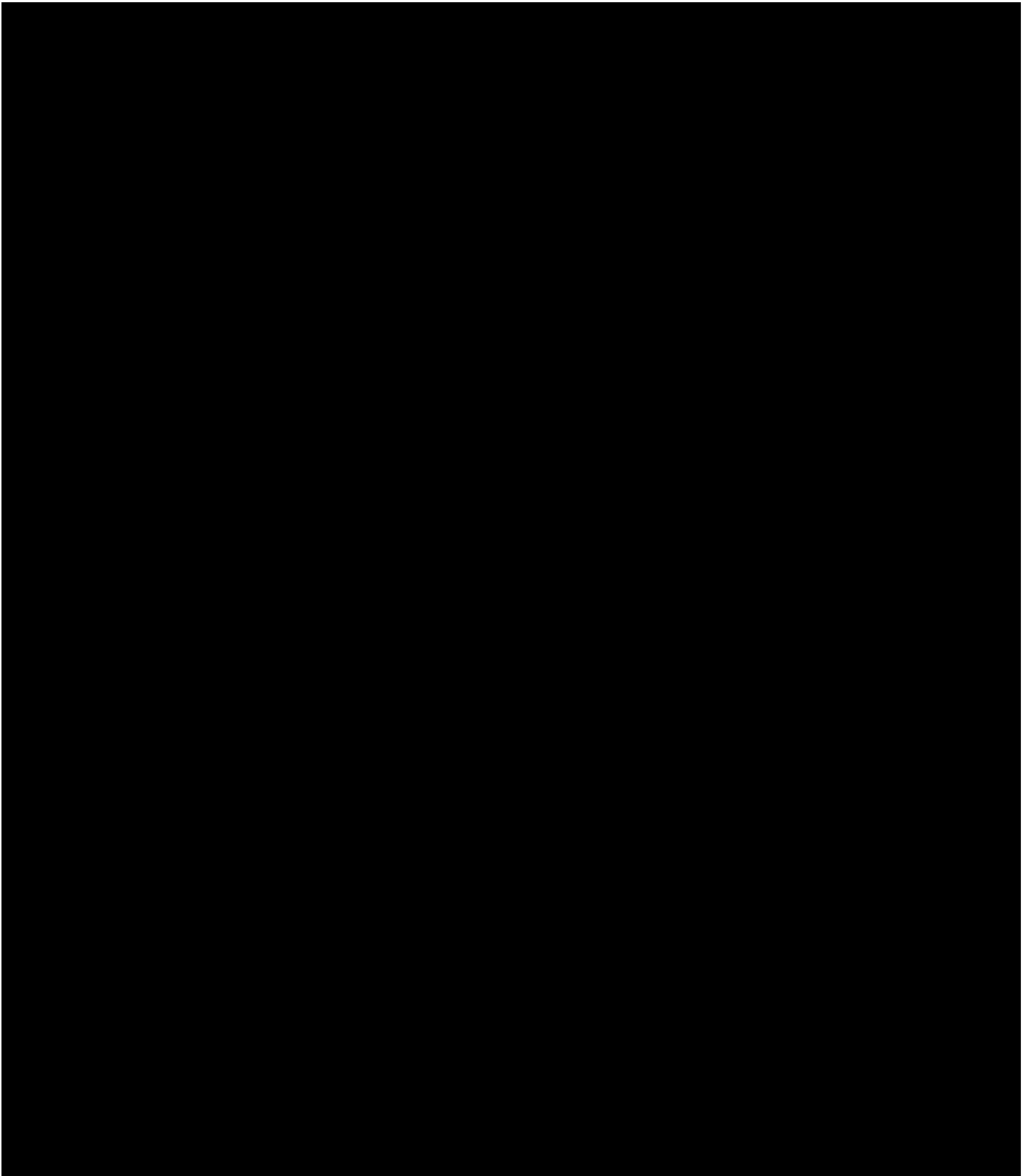
- c. **1[b]: a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet, and a second operating mode in which: a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet,**

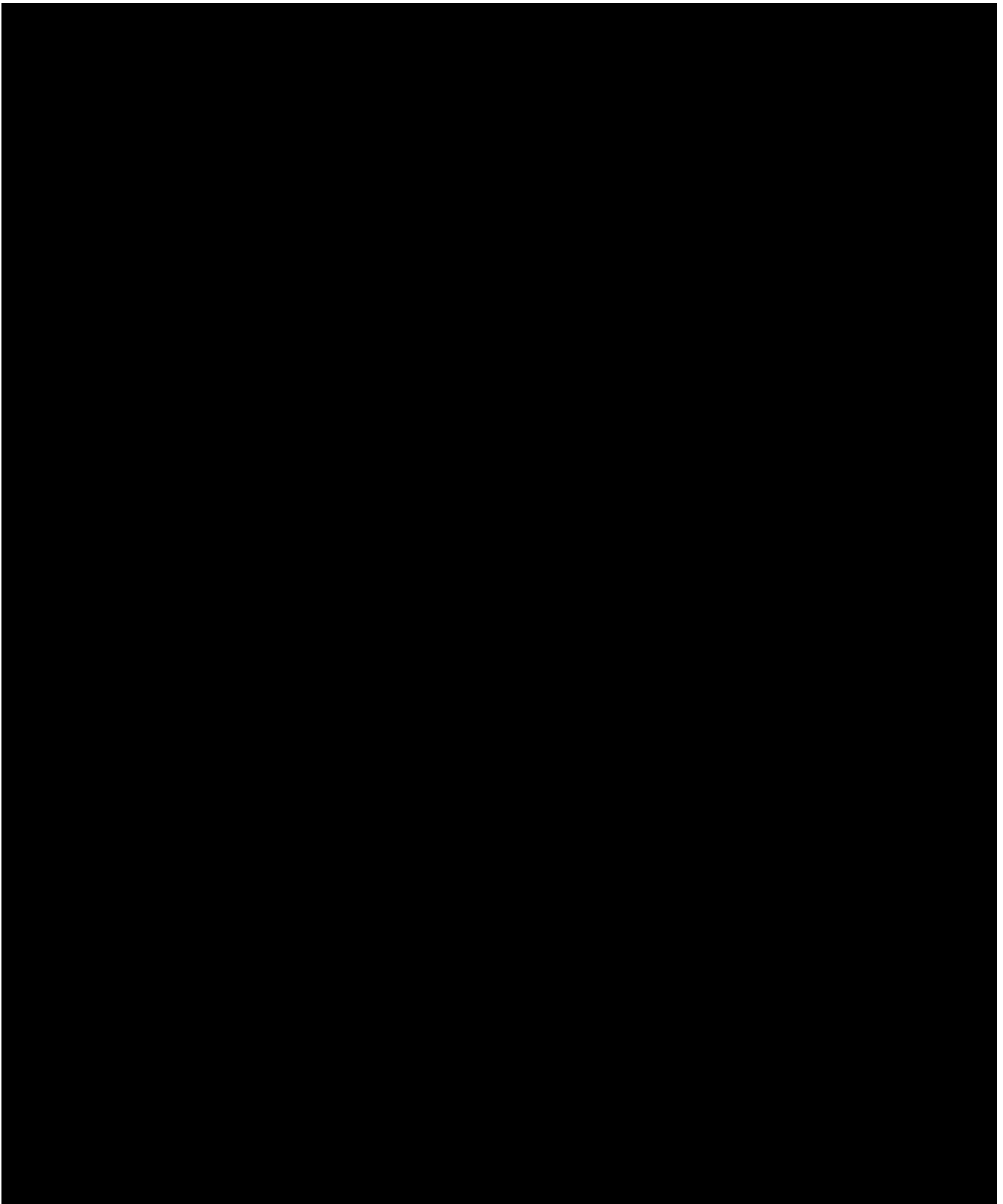
139. The Court construed the term “diverter” to be a means-plus-function term (D.I. 75 at 2):

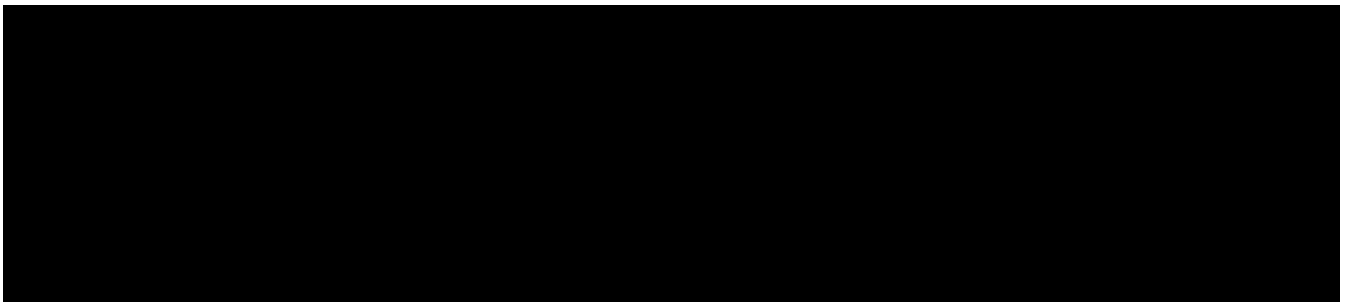
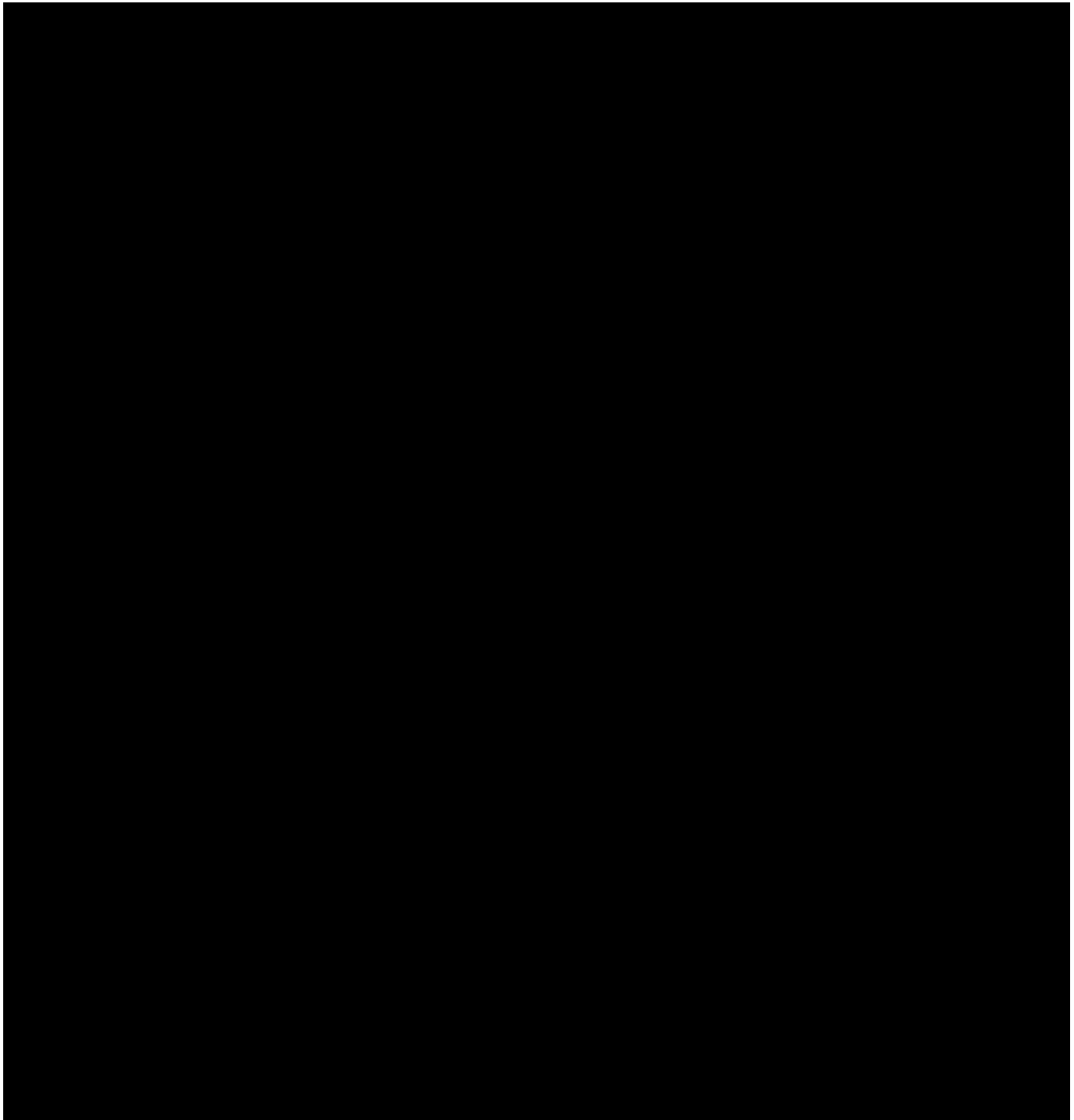


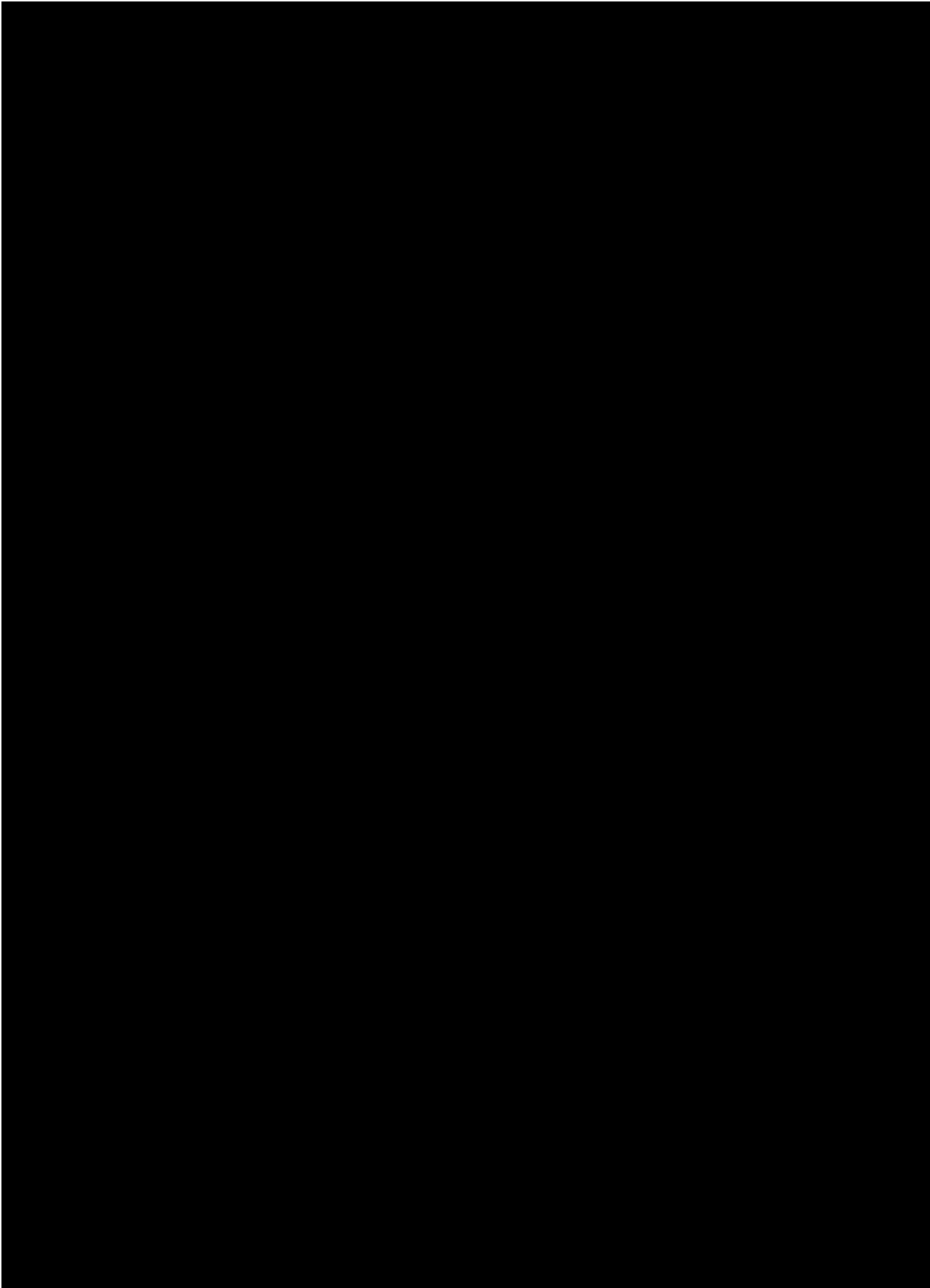


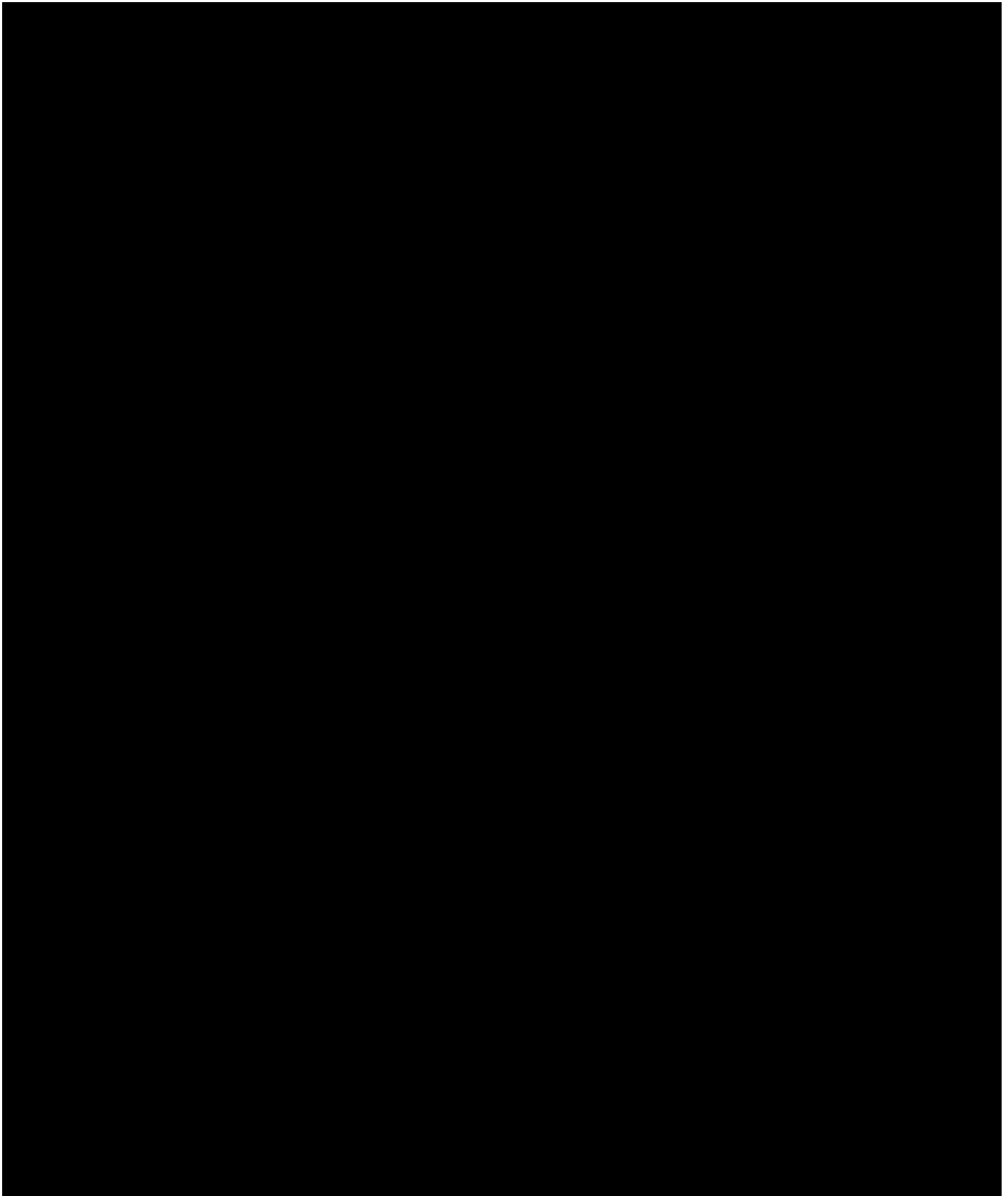


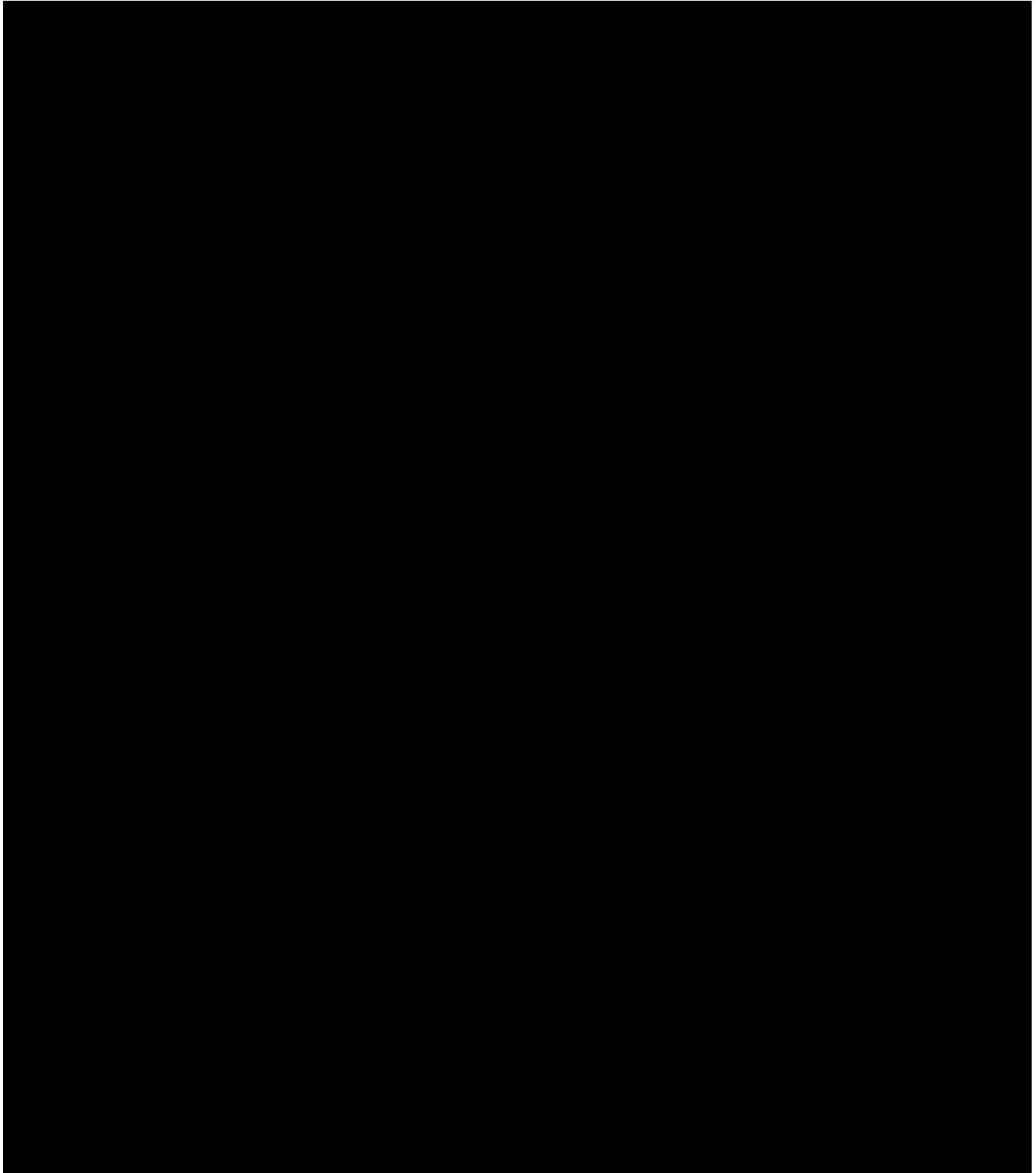


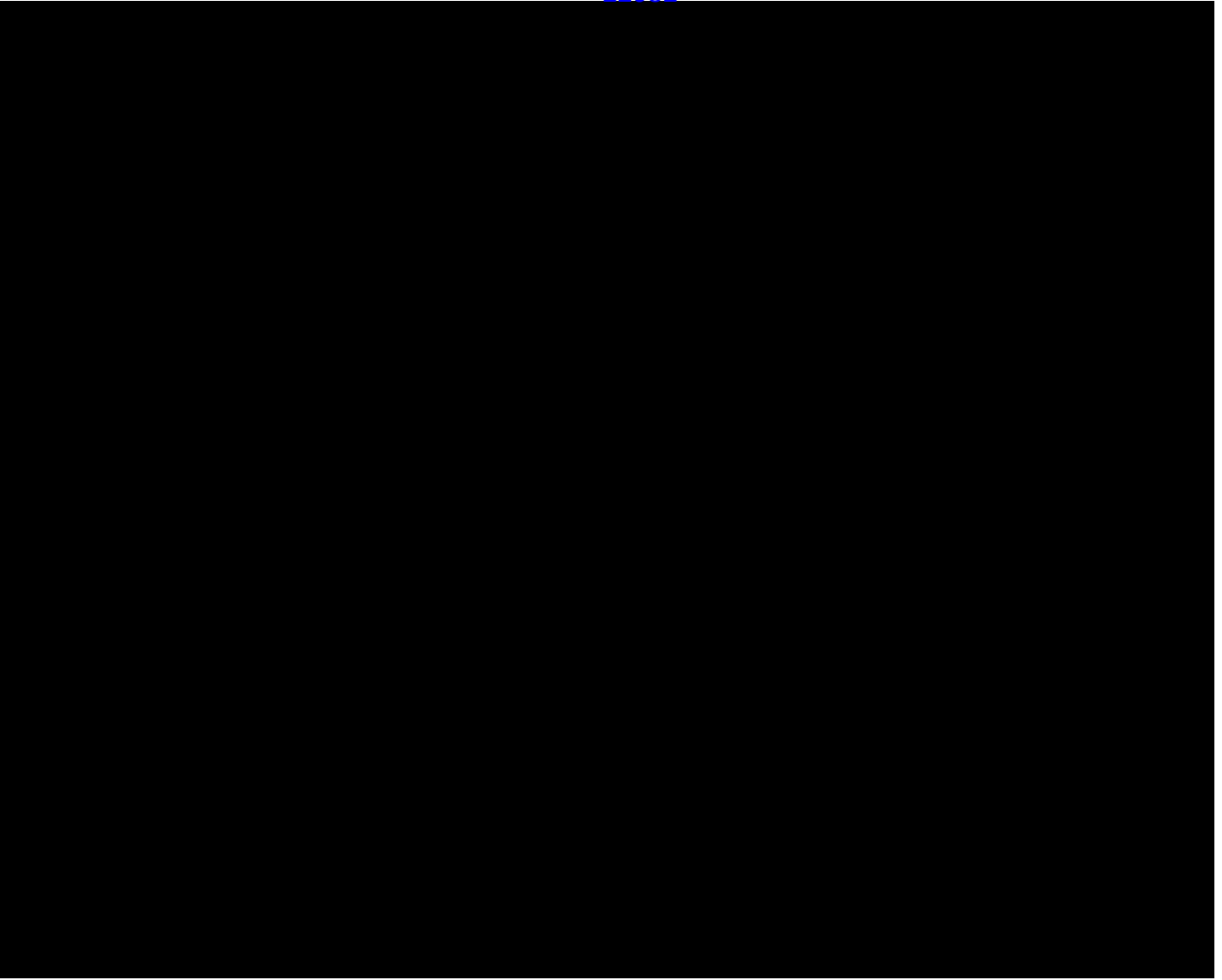


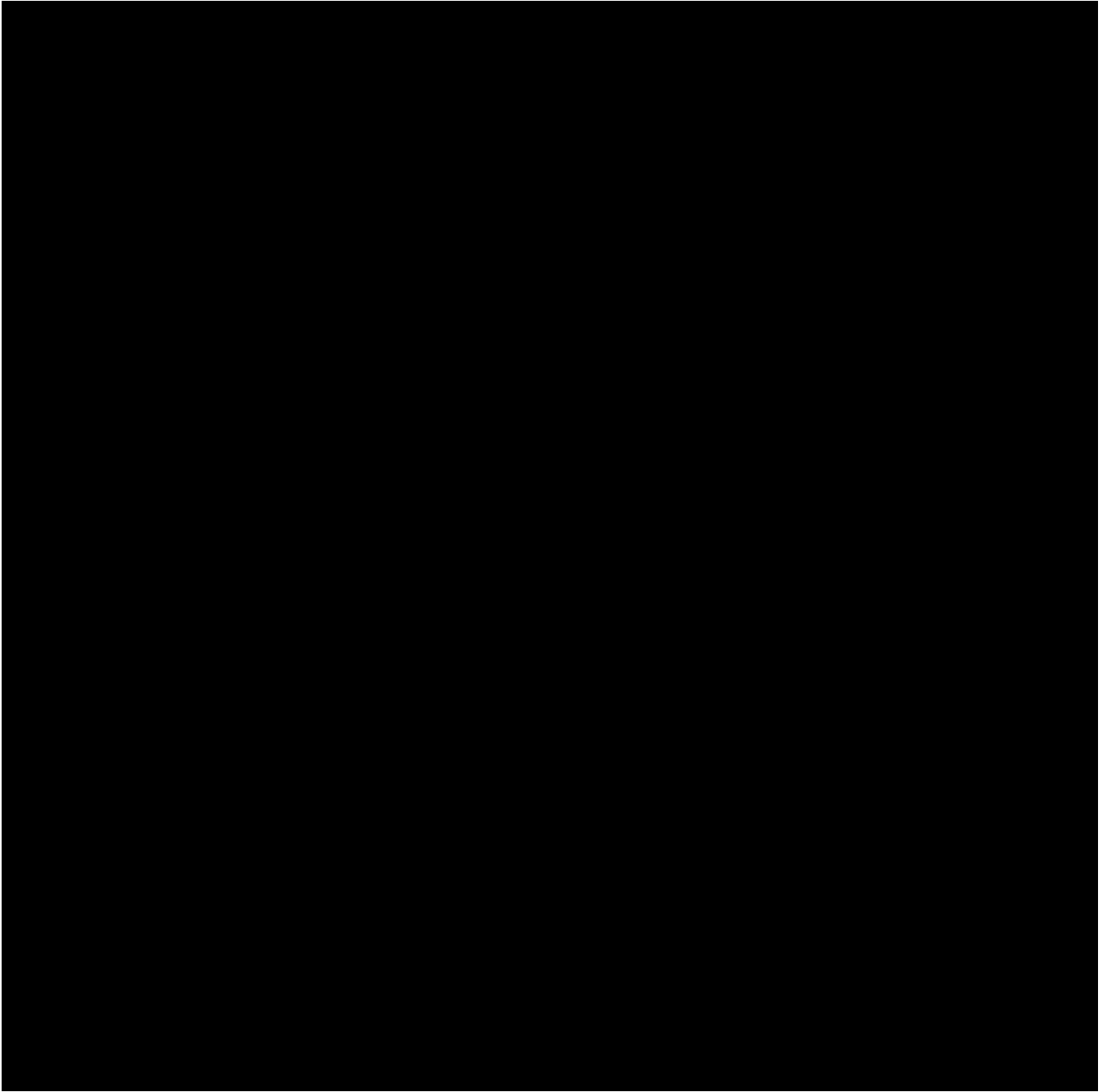


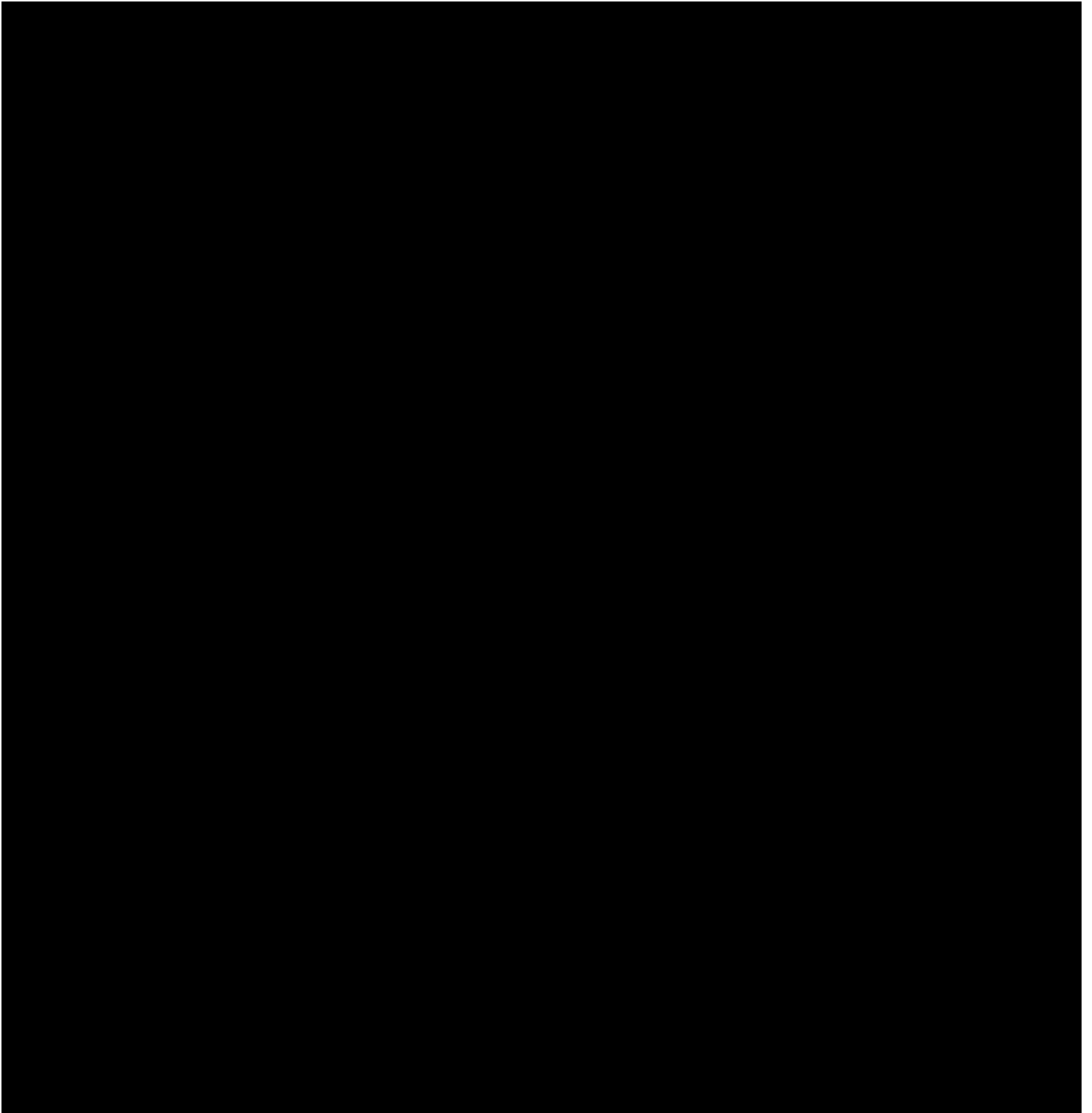


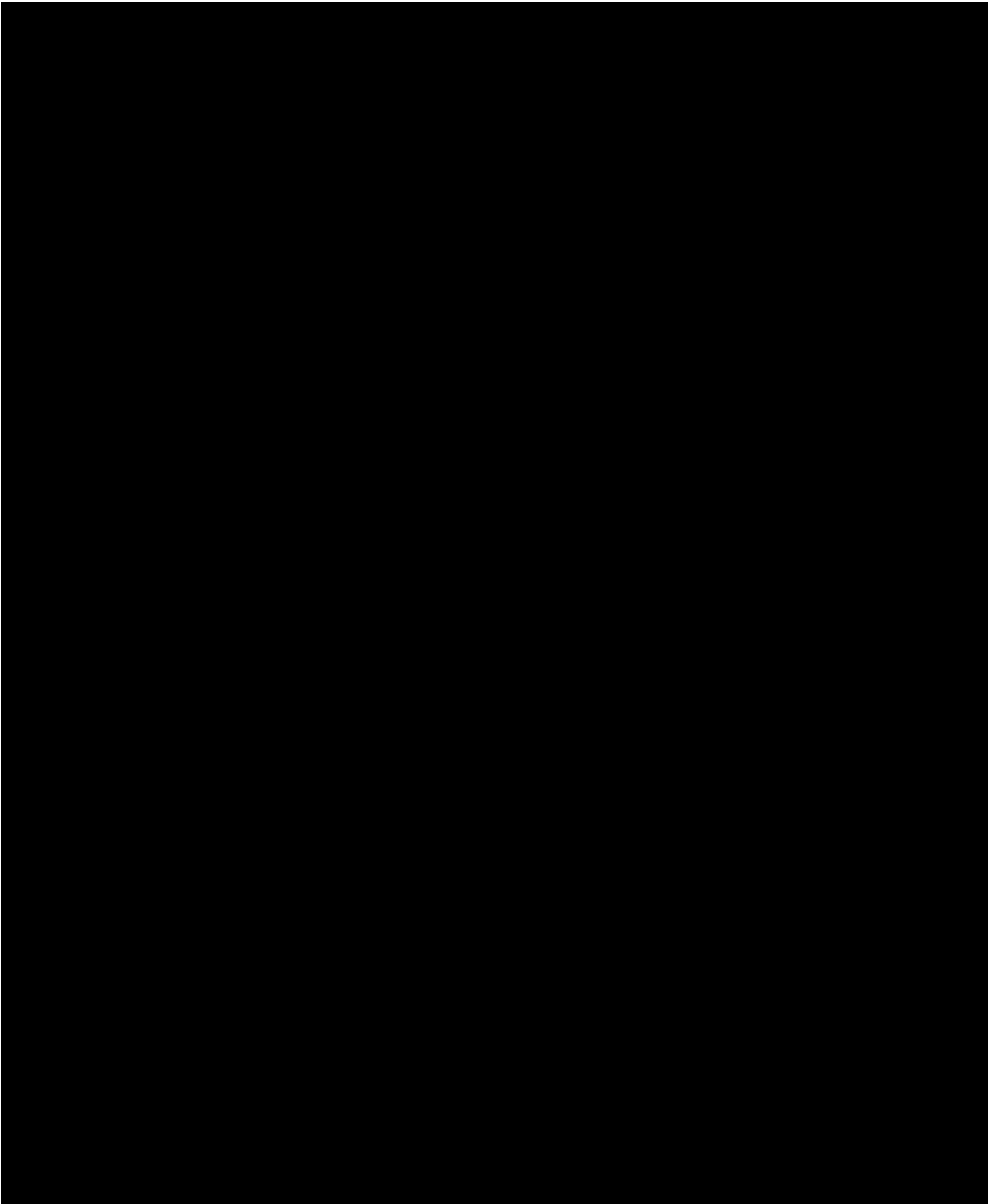


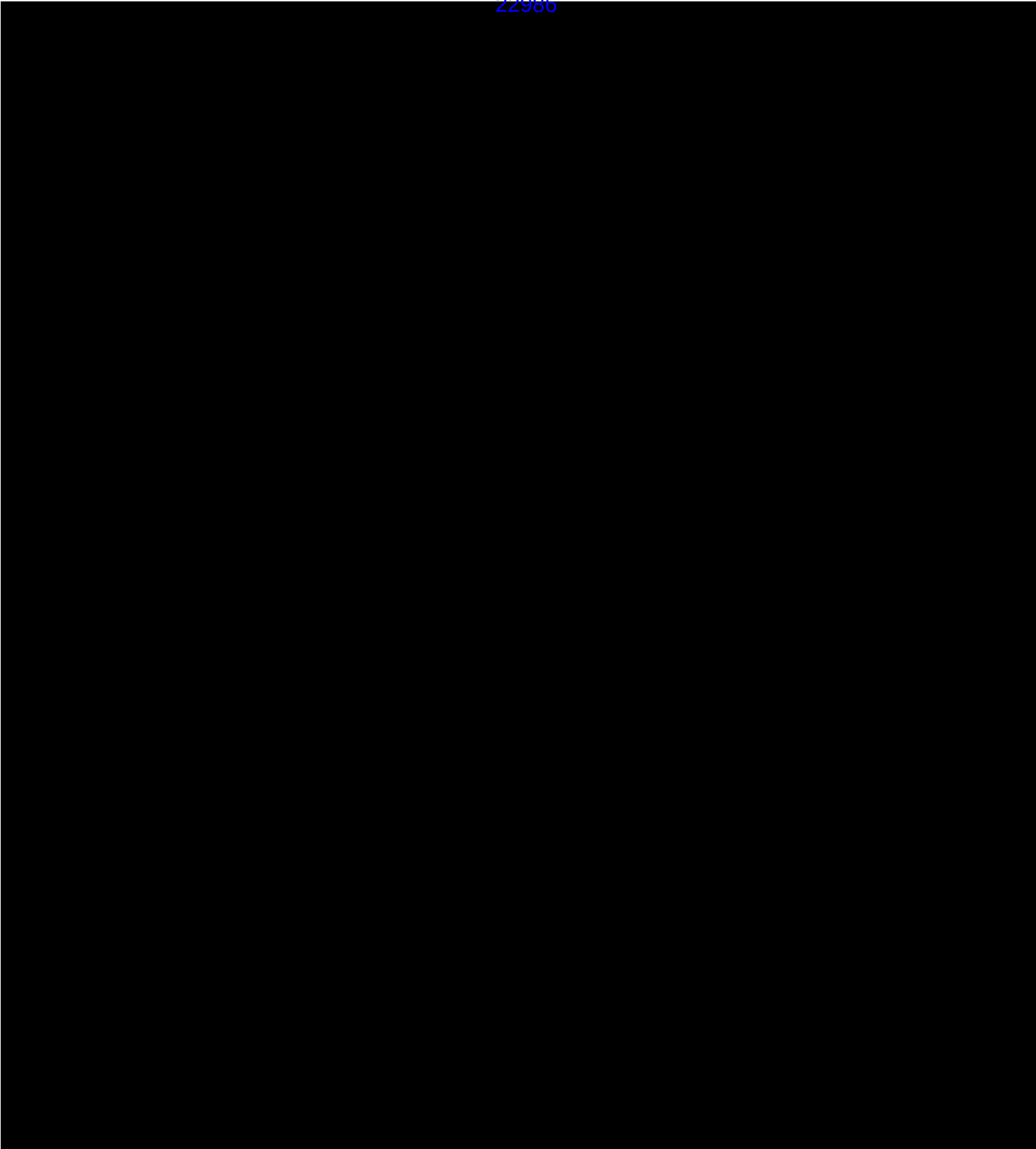


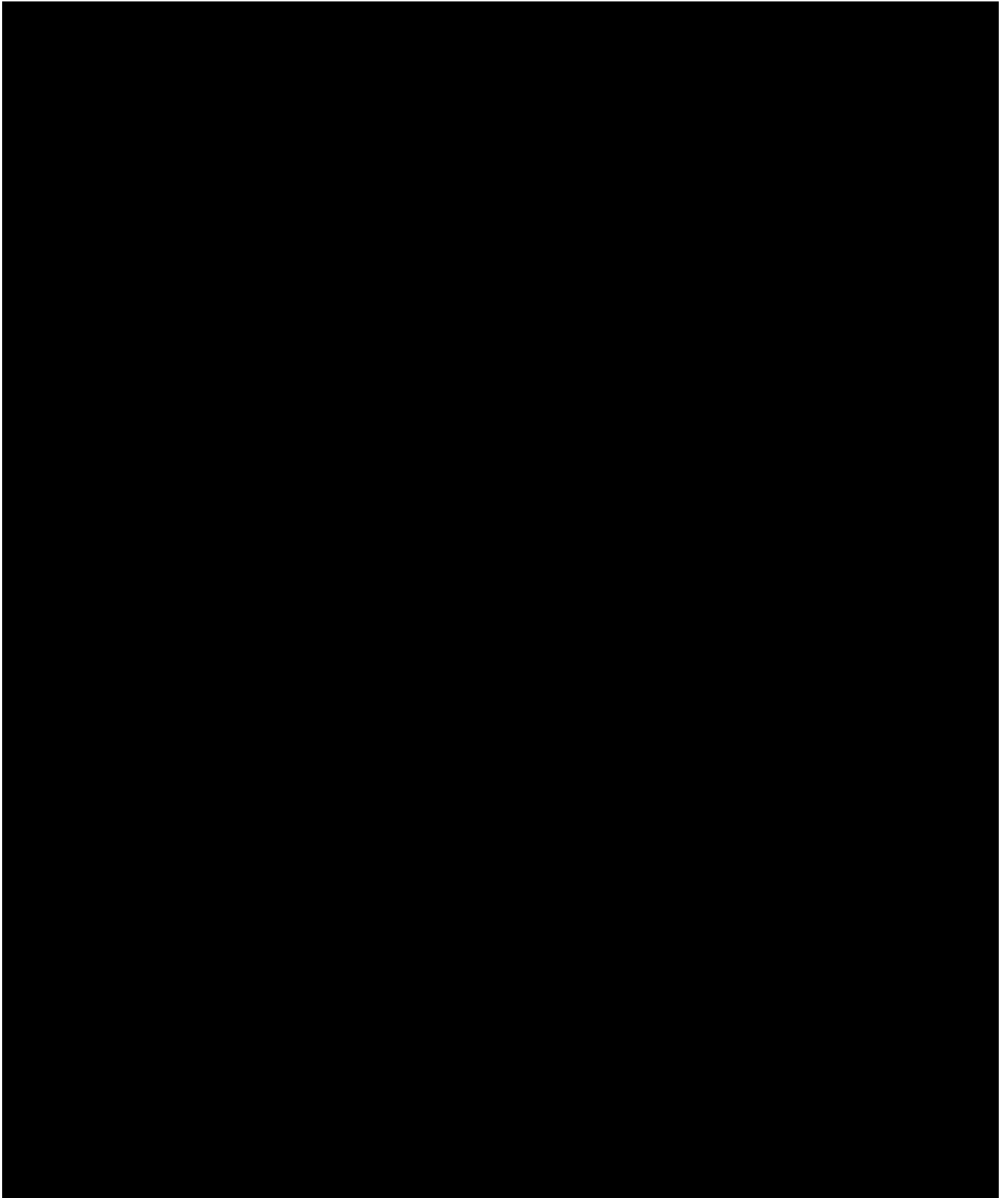


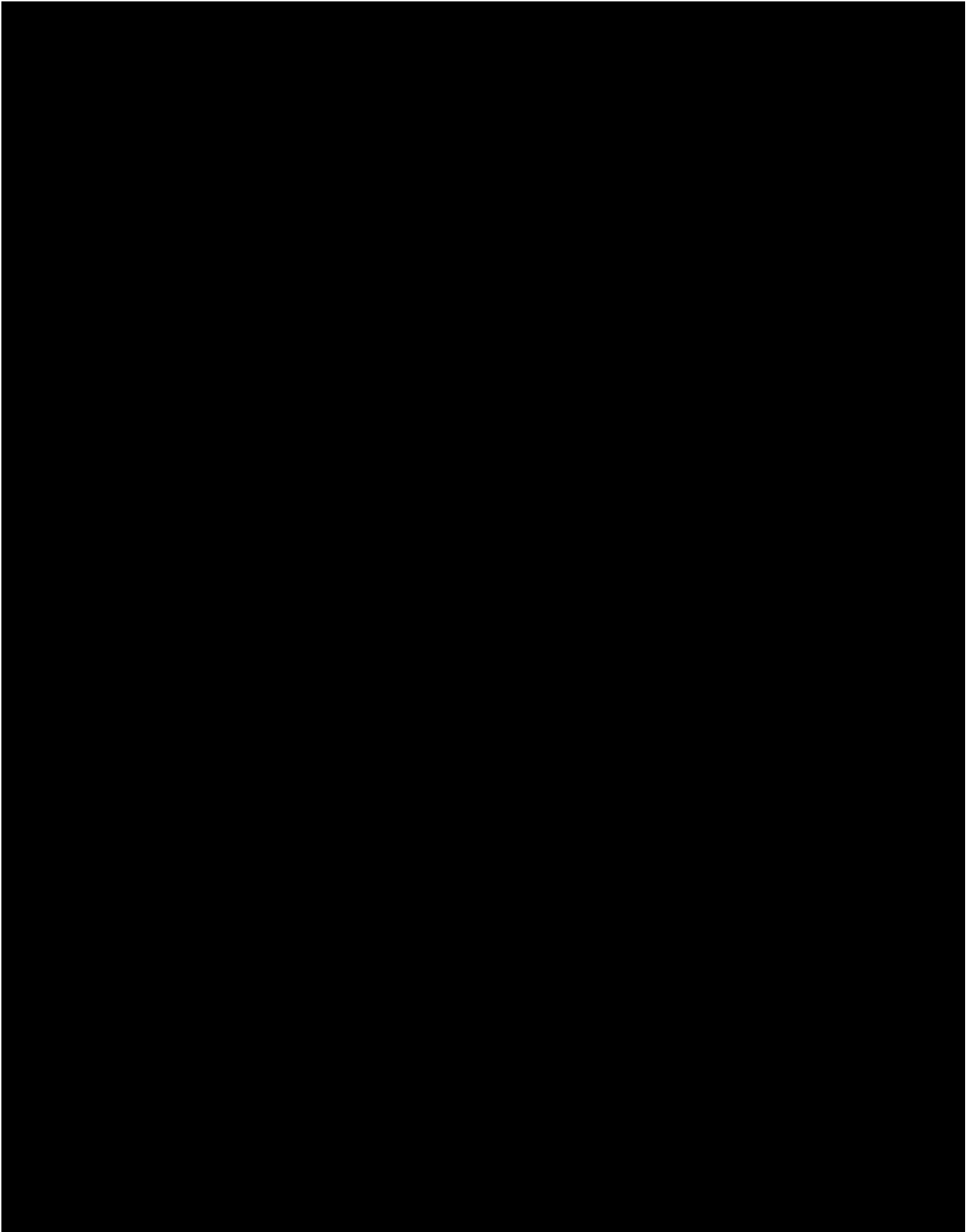


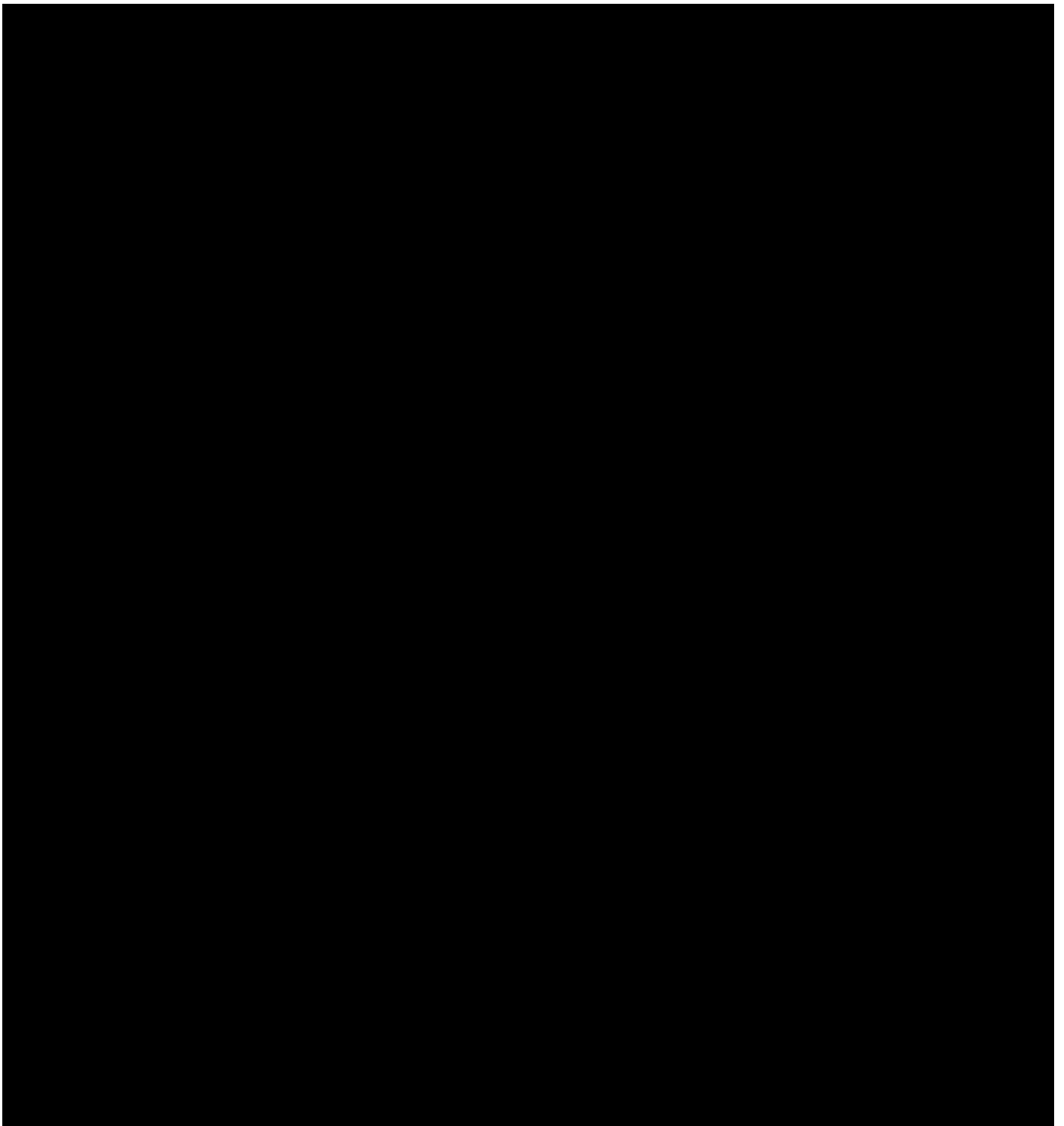


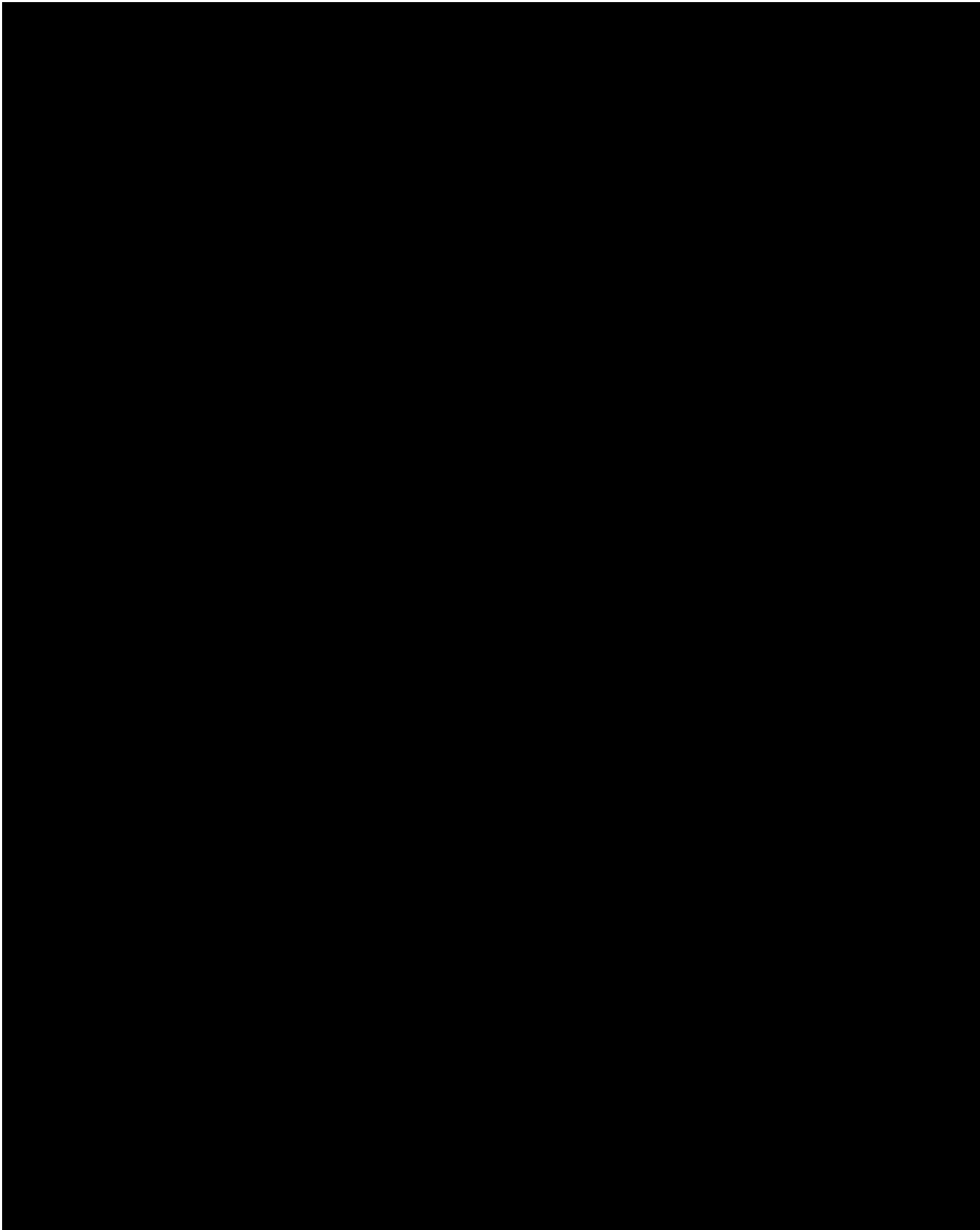


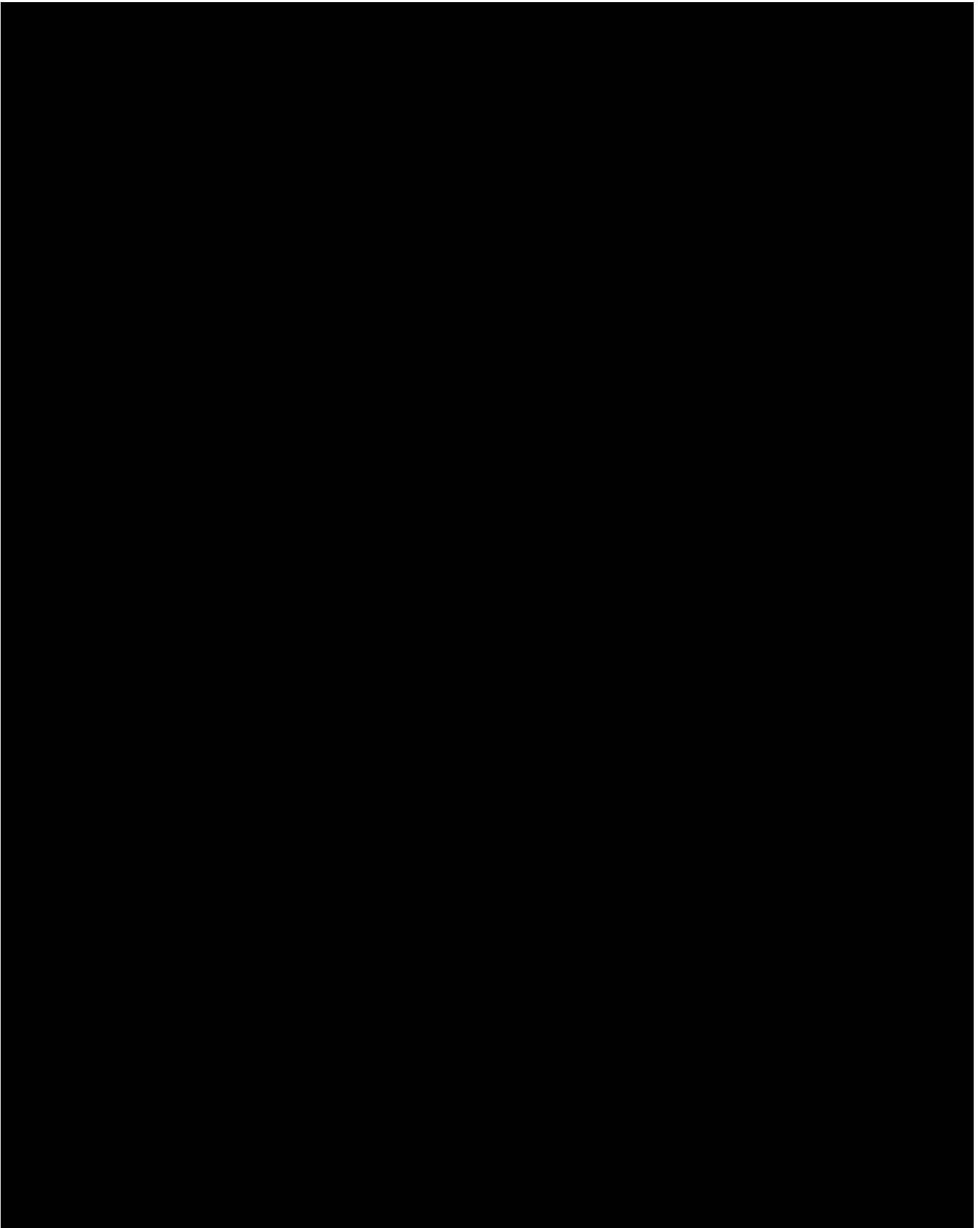


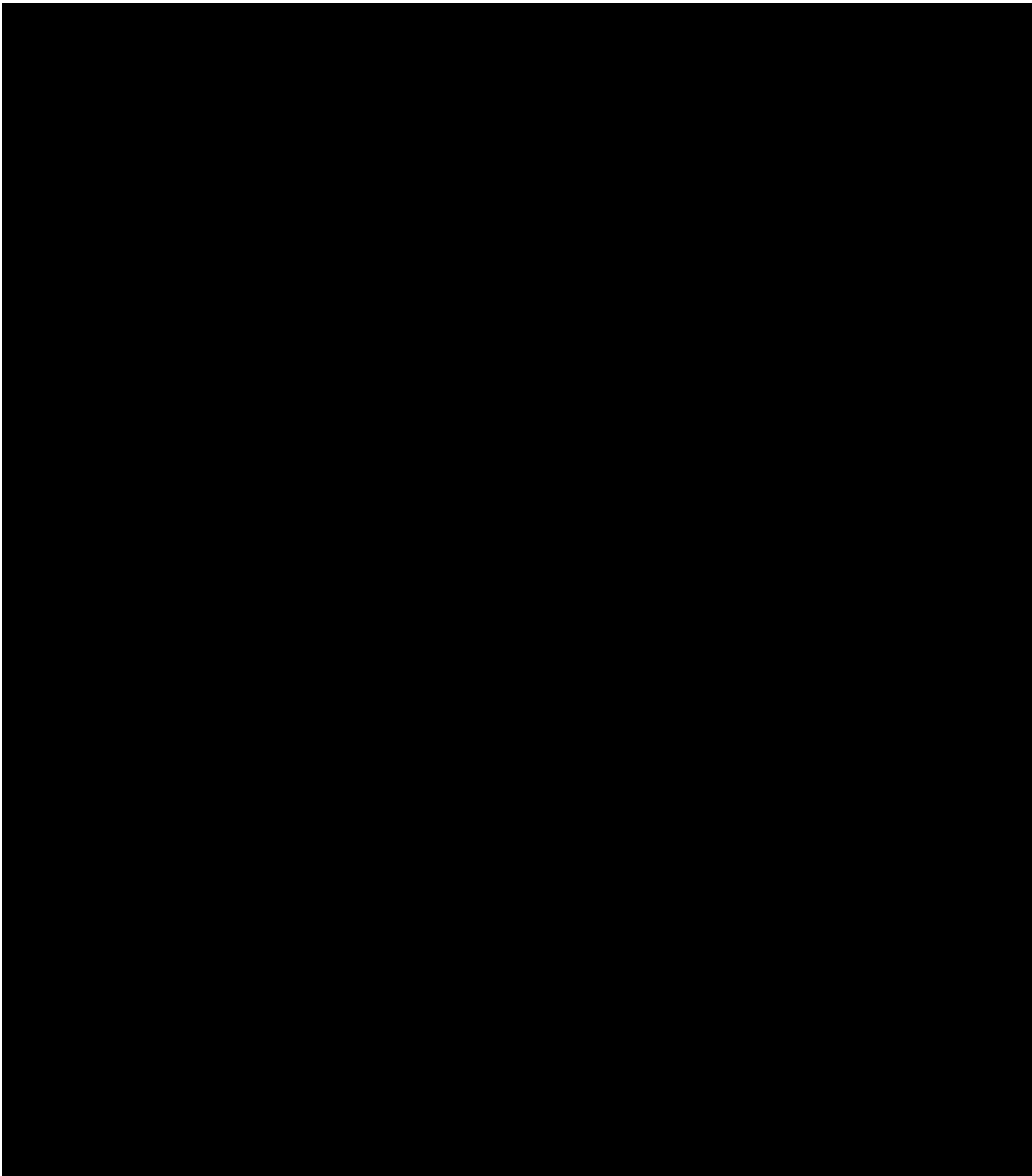


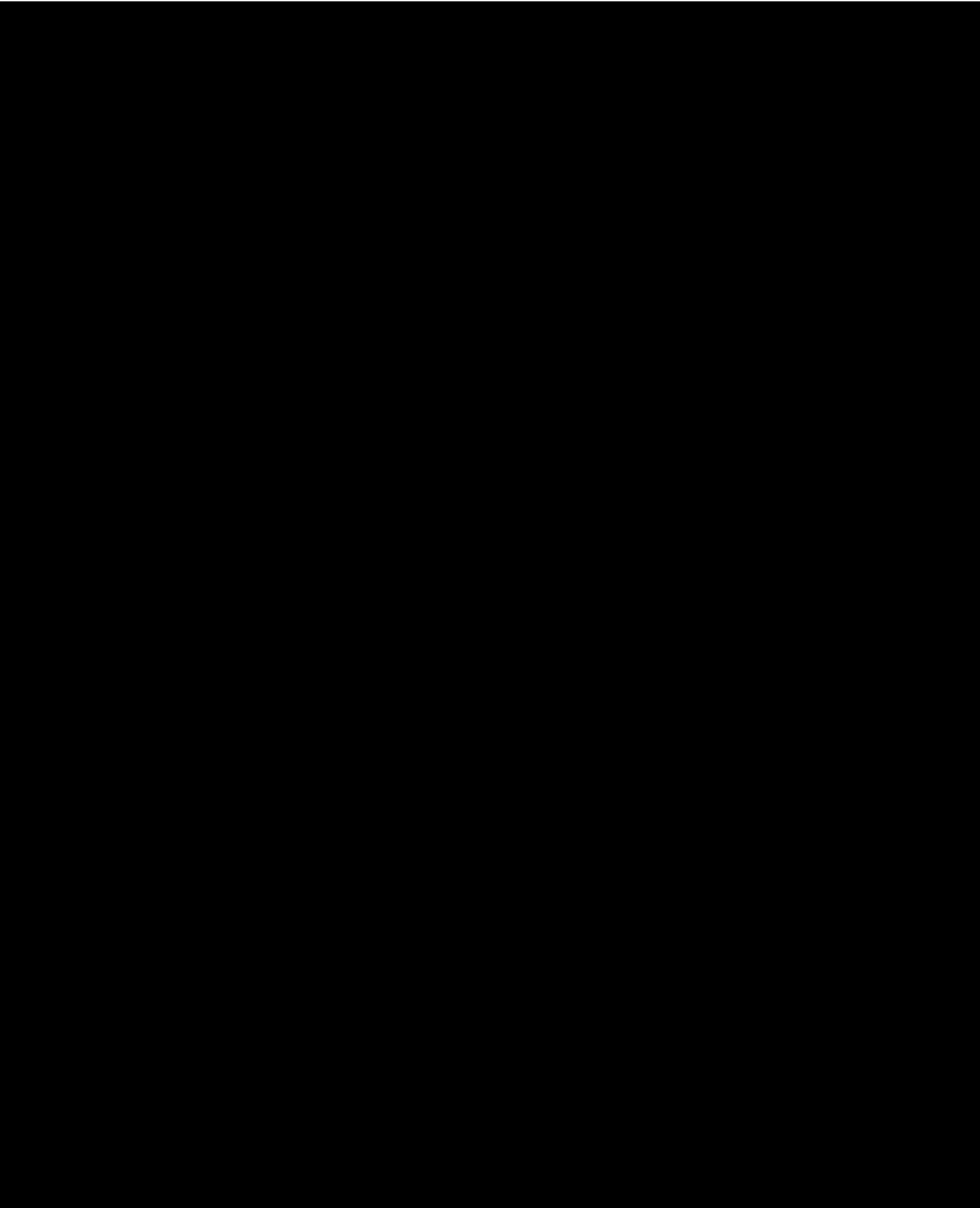




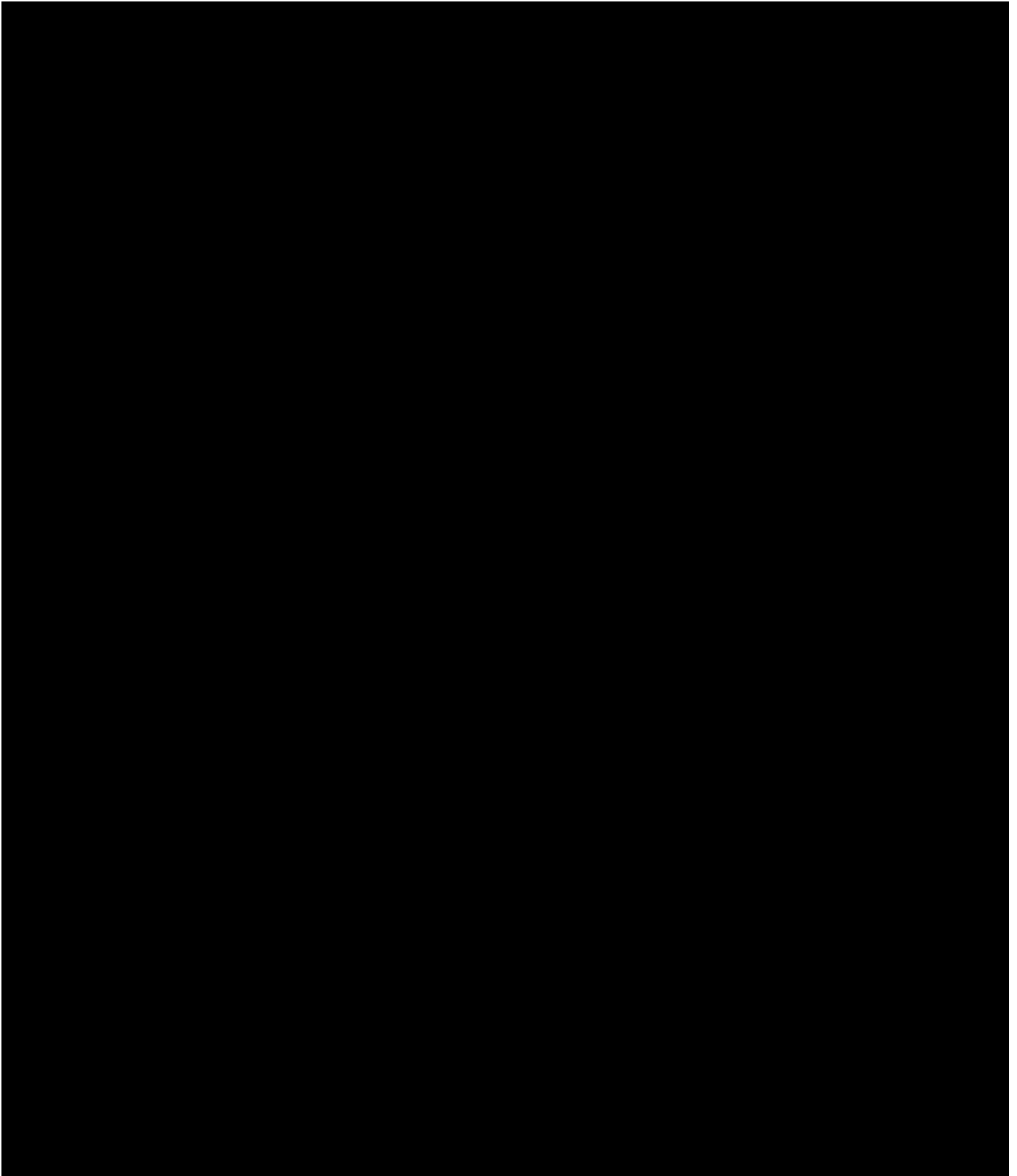


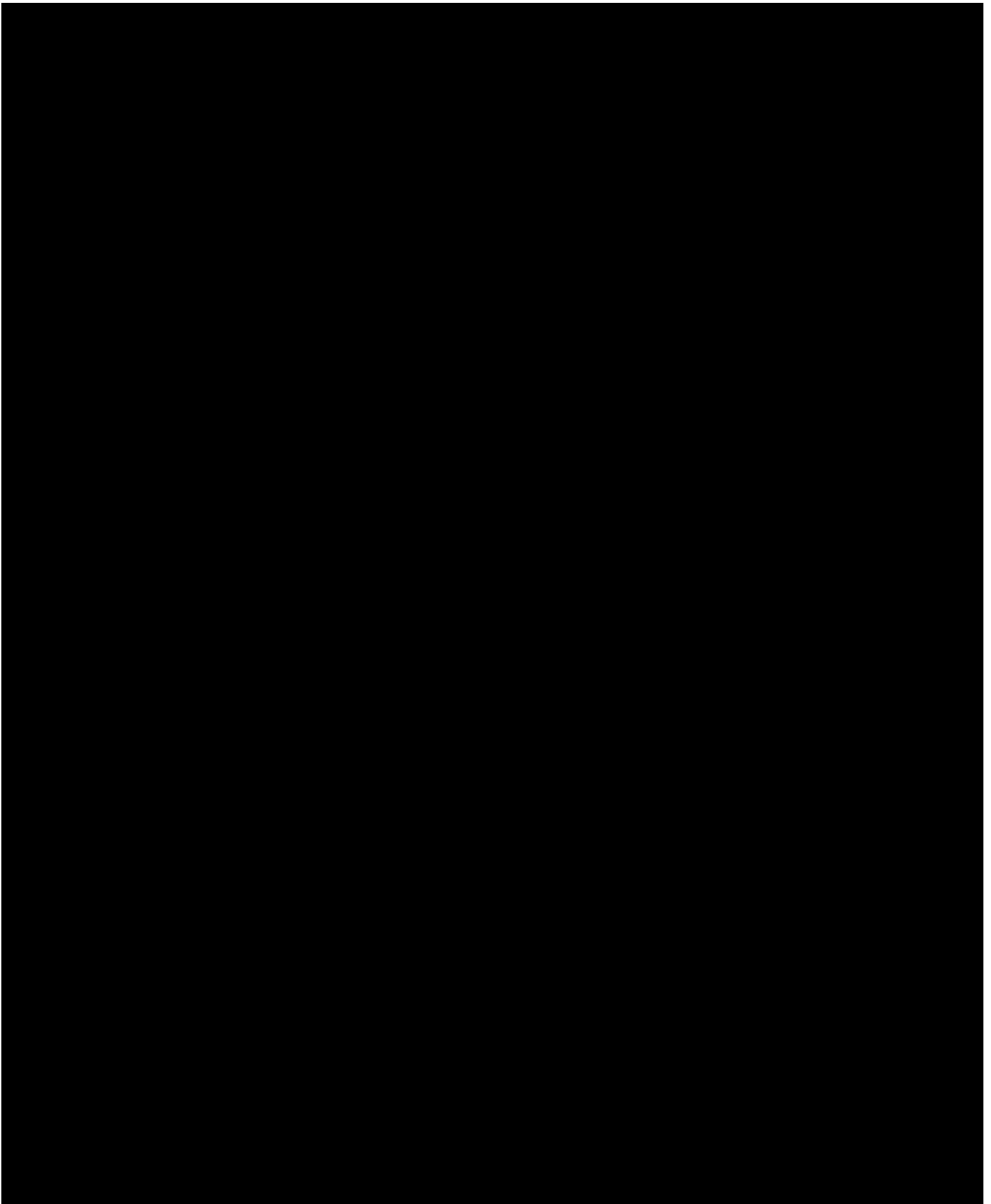


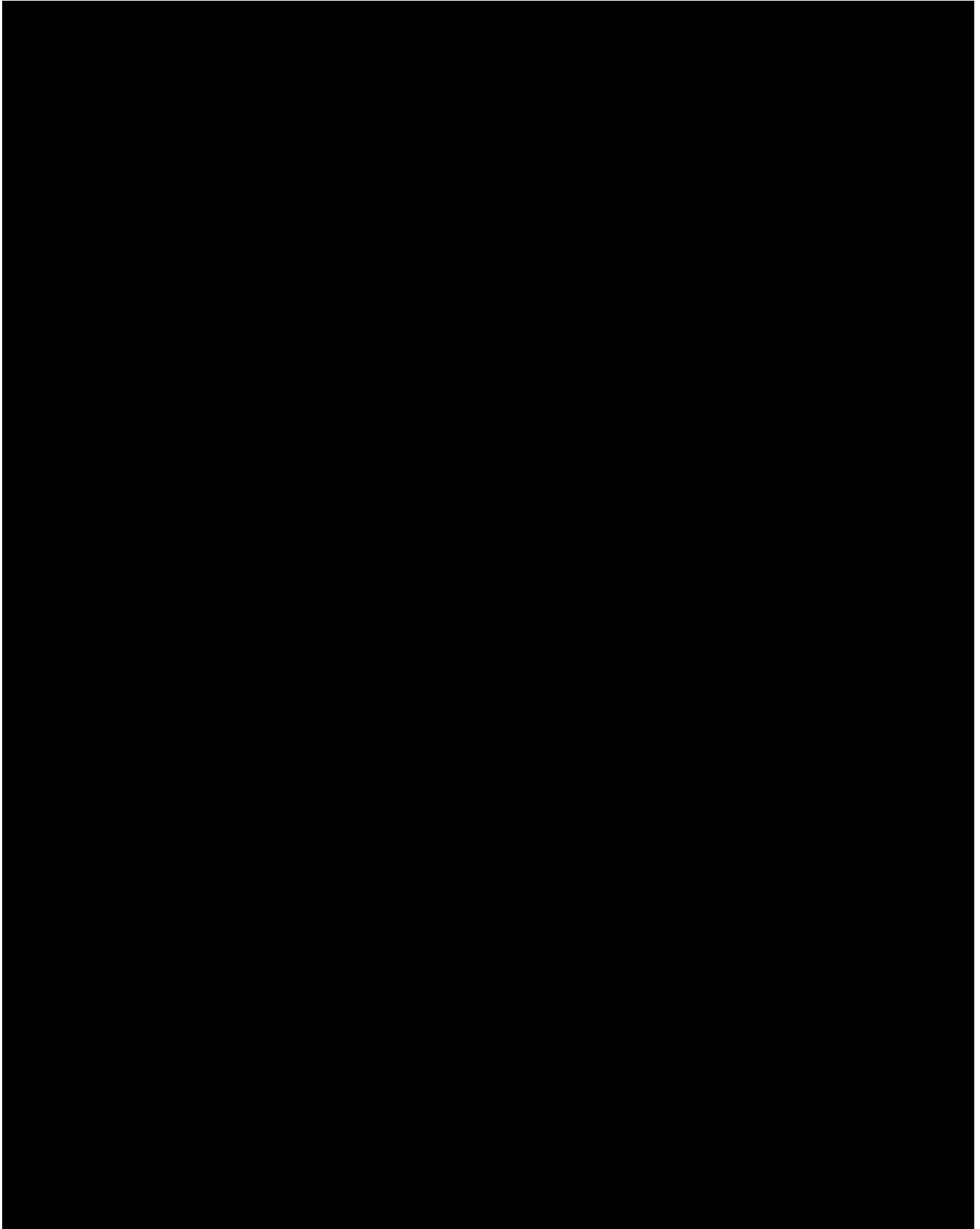


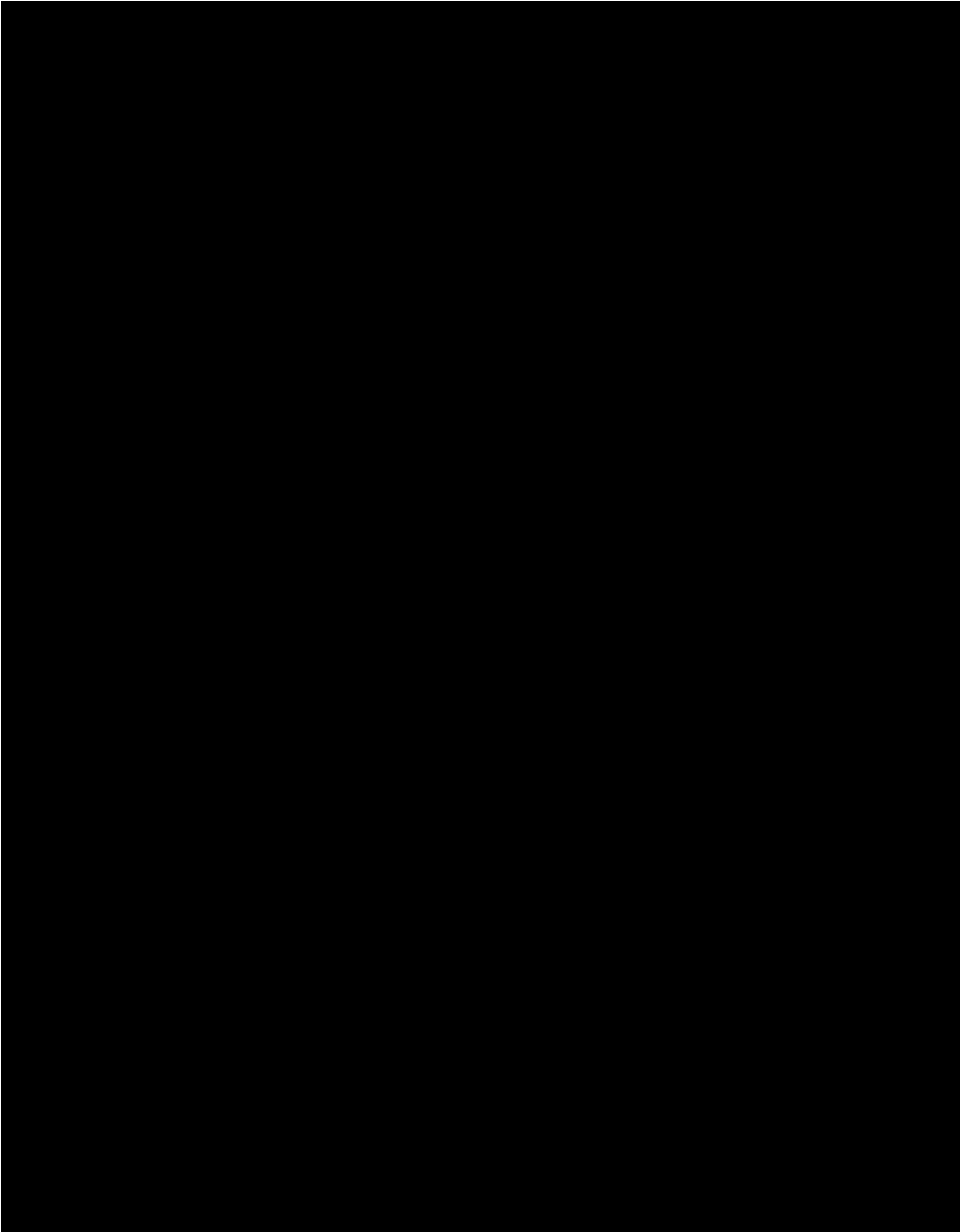


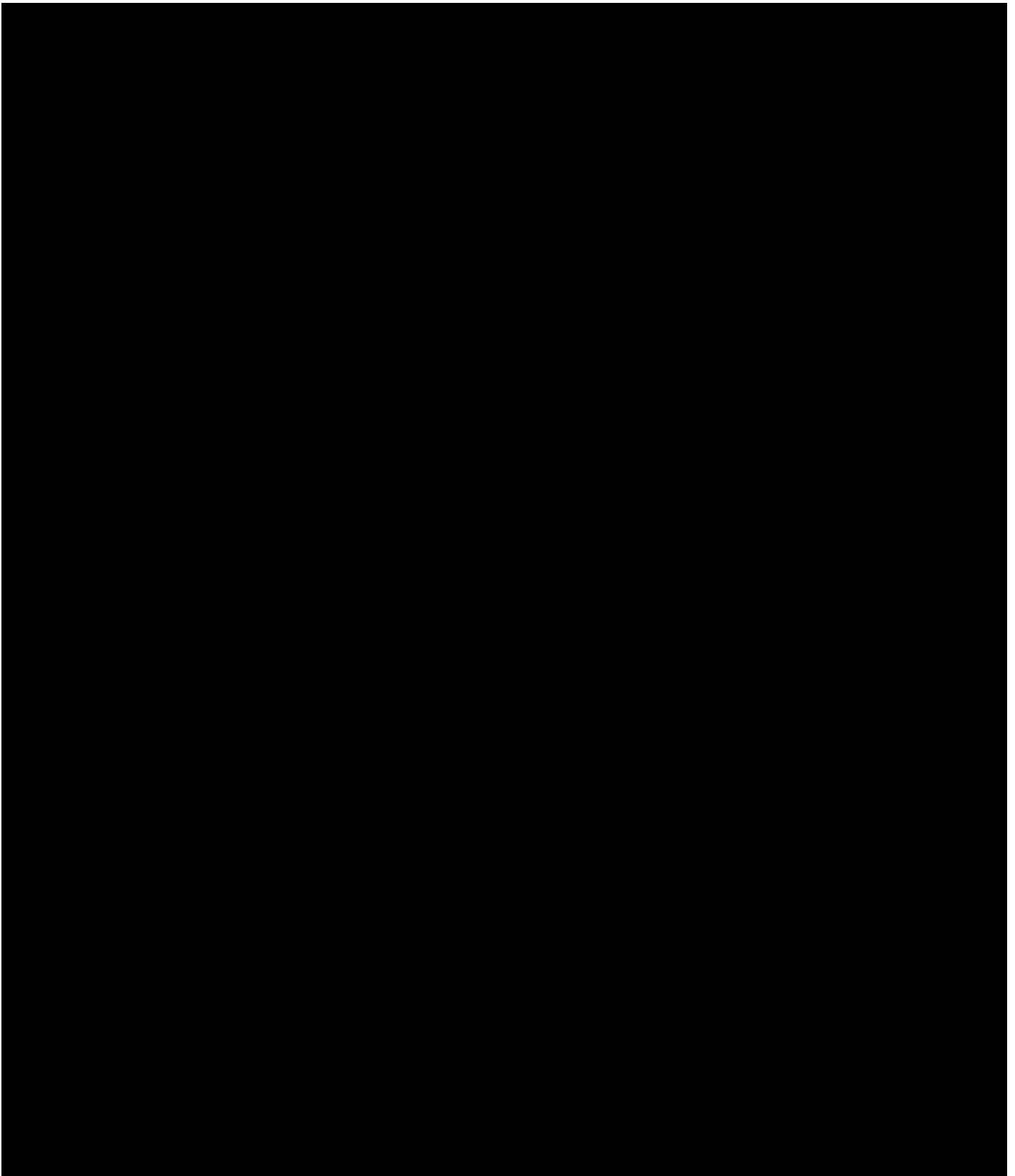
CONFIDENTIAL — PURSUANT TO PROTECTIVE ORDER











initial volume of bodily fluid, thereby reducing contamination of the subsequent volume of bodily fluid withdrawn from the patient.

179. In the Kurin Lock device's first operating mode, the patient's blood pressure is greater than the air pressure escaping from the reservoir through the porous plug. [REDACTED]

[REDACTED] Flow toward the plug is arrested as the porous plug valve absorbs moisture from blood and swells. The pressure difference within the liquid volume of the U-shaped diversion chamber progressively decreases in magnitude as the plug seals completely. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The reduction in the bulk velocity of blood flow within the reservoir is consistent with a reduction in the magnitude of the axial pressure differences along the channel. In the Kurin Lock device's second operating mode, when the porous plug valve or umbrella valve closes, the pressure differential in the reservoir equalizes and the flow is completely arrested. Once the magnitude of pressure differences are sufficiently decreased, the diverter transitions operating mode by

causing the meniscus at the second outlet (the liquid-air interface) to burst so that some blood enters into the second daughter channel. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

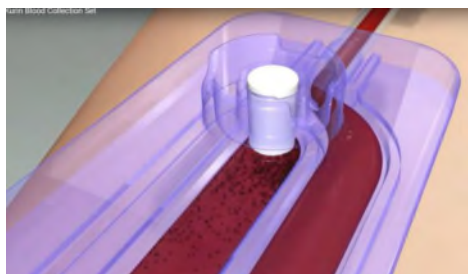
[REDACTED]

180. In the first operating mode, the blood flows into the U-shaped side channel. As the initial volume of blood fills the U-shaped side channel and the porous plug seals, the pressure from the blood in the U-shaped side channel equalizes with the patient's blood pressure, which causes the second mode of operation where the blood is directed down the sample channel:

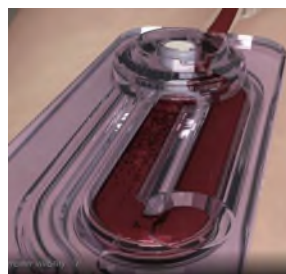
MAG-DEL0000838 (Kurin Video 07/09/2019) at 0:23-54 ("The initial flow of blood, and any contaminants therein, fills a U-shaped side channel until it reaches a white porous seal.... When in contact with the blood, the seal material is activated to lock the channel so that blood cannot exit and air cannot enter, blocking the initial blood and contaminants in place. With the

side channel sealed, a small amount of blood will bypass the contents of the side channel, flowing directly into the collection passage. The blood will advance a variable distance before automatically stopping to indicate that the set is ready for collection bottle attachment.”); MAG-DEL0826802 (Kurin Video 01/2021) (“With venous access, the initial flash of blood—and contaminants within—fills a U-shaped side channel until it reaches a white porous plug. Kurin requires only about 0.15mL of precious blood, making the device ideal for peds and patients at risk for hypovolemic anemia. Although 0.15ml is a small amount, it is enough to wash out a 21 gauge needle 35 times. Once the side channel is full, blood will flow a variable distance into the adjoining sampling channel before stopping. This indicates that the set is ready for specimen collection.”)

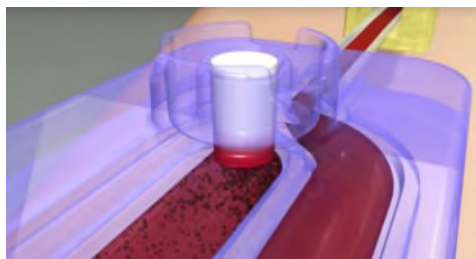
MAG-DEL0000838 at 0:30:



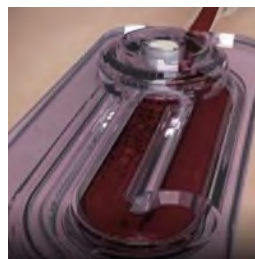
MAG-DEL0826802 at 0:22:



MAG-DEL0000838 at 0:39:

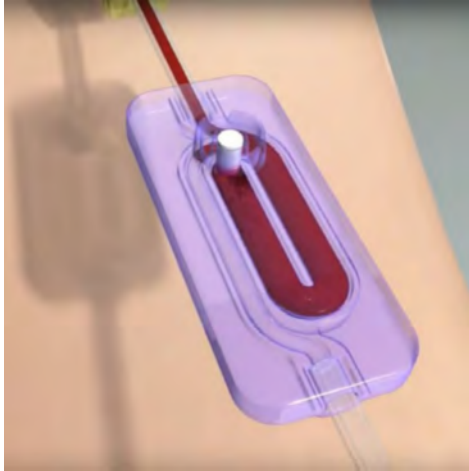


MAG-DEL0826802 at 0:47:



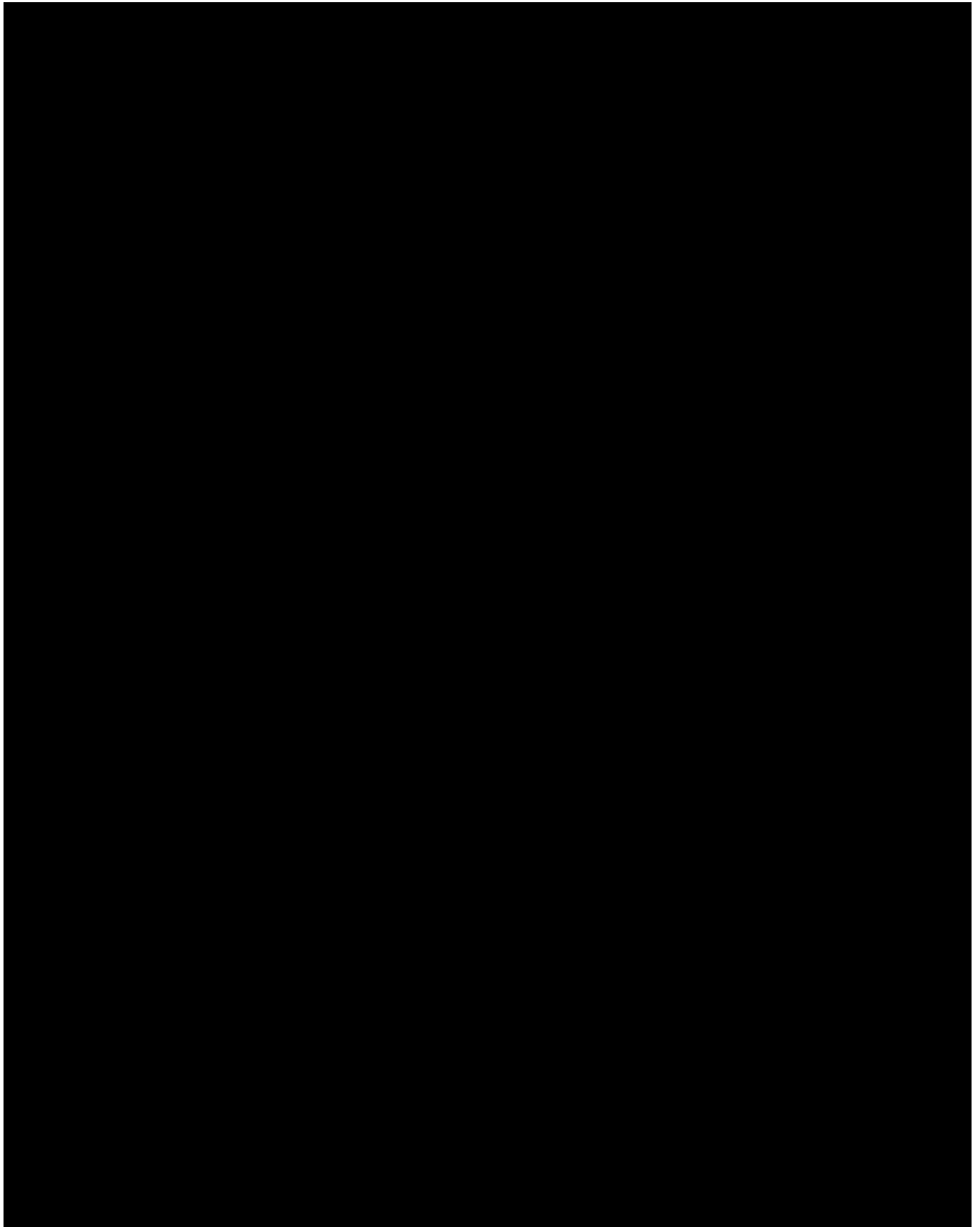
MAG-DEL0000838 at 0:48:

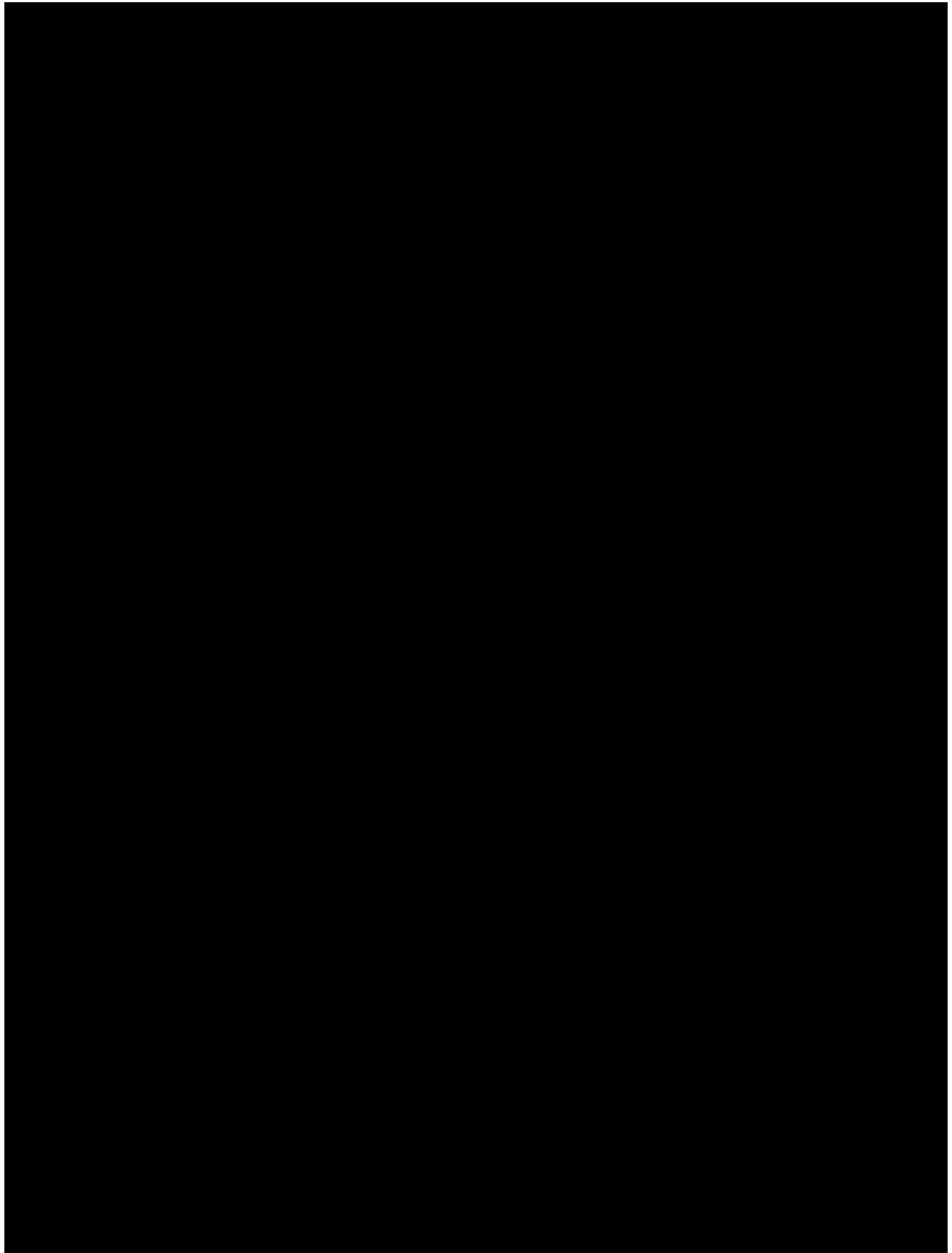
MAG-DEL0826802 at 0:47:

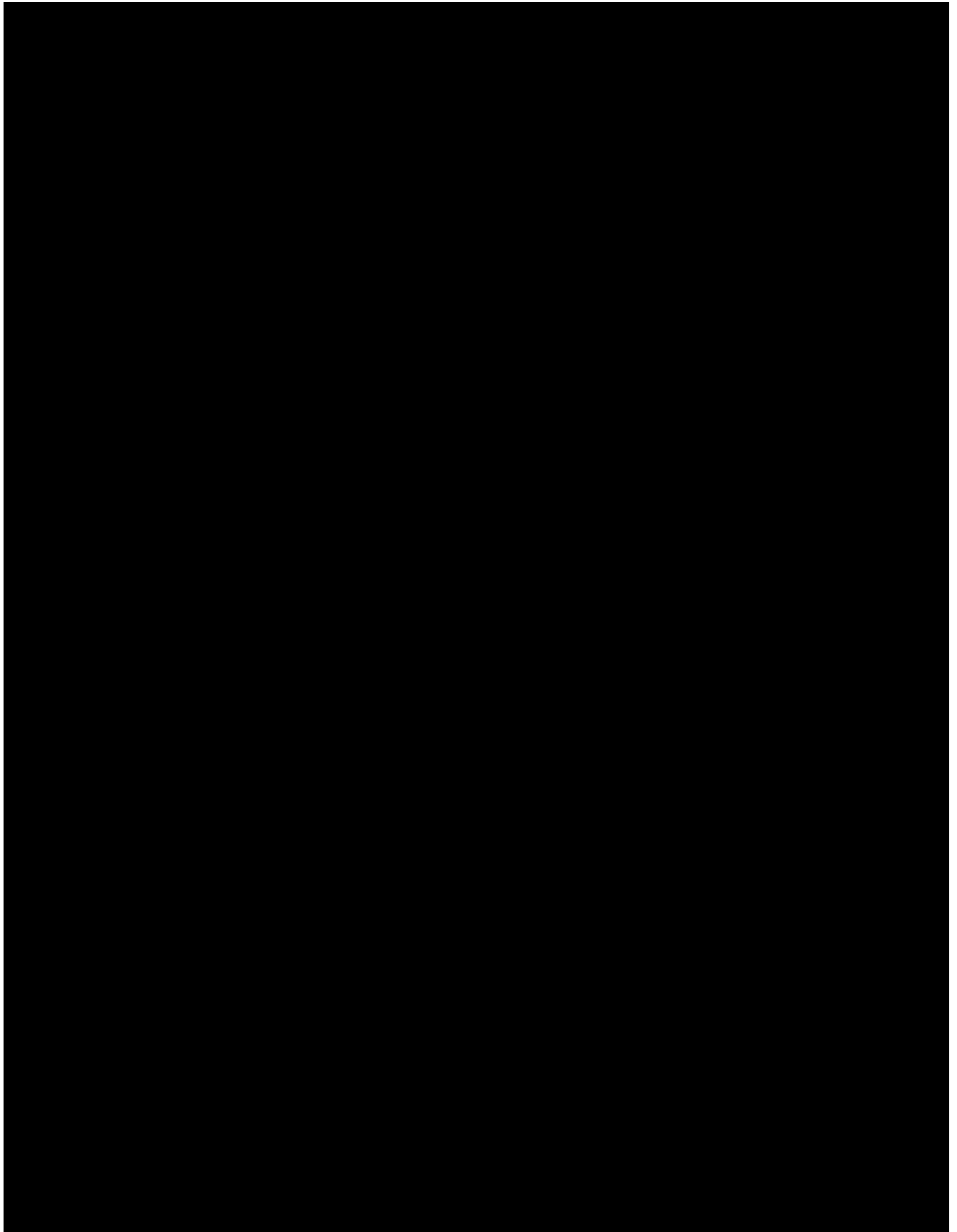


MAG-DEL0000663–670 (K162233 Summary) at 669 (“Principles of operation – The winged needle is used to access the patient’s blood stream...the kurin component sequesters the initial sample of blood and the vial adapter is used to interface with a vacuum tube or culture bottle. There is no energy source, the subject device fills with blood by difference in pressure gradient.”).

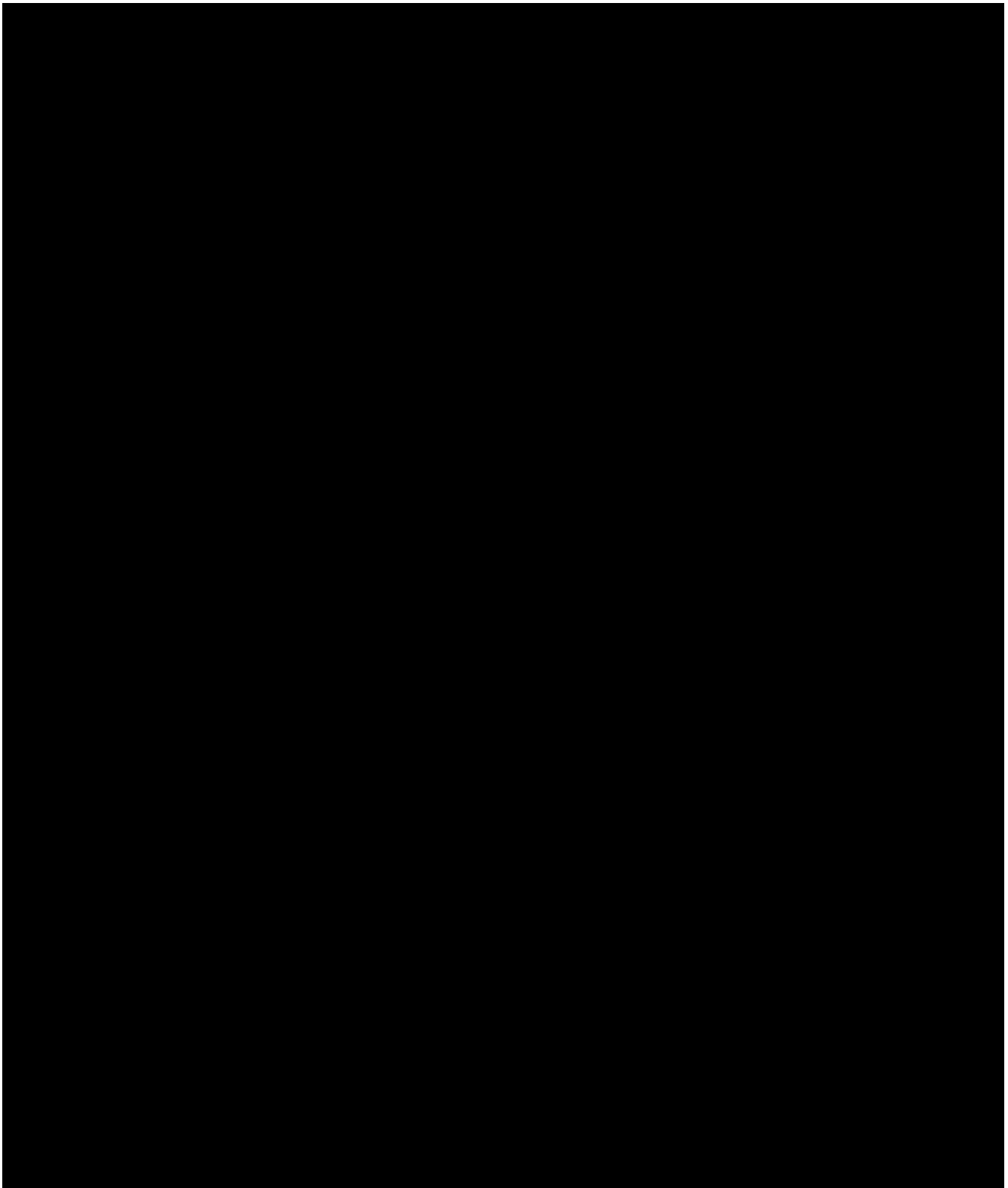
[REDACTED]











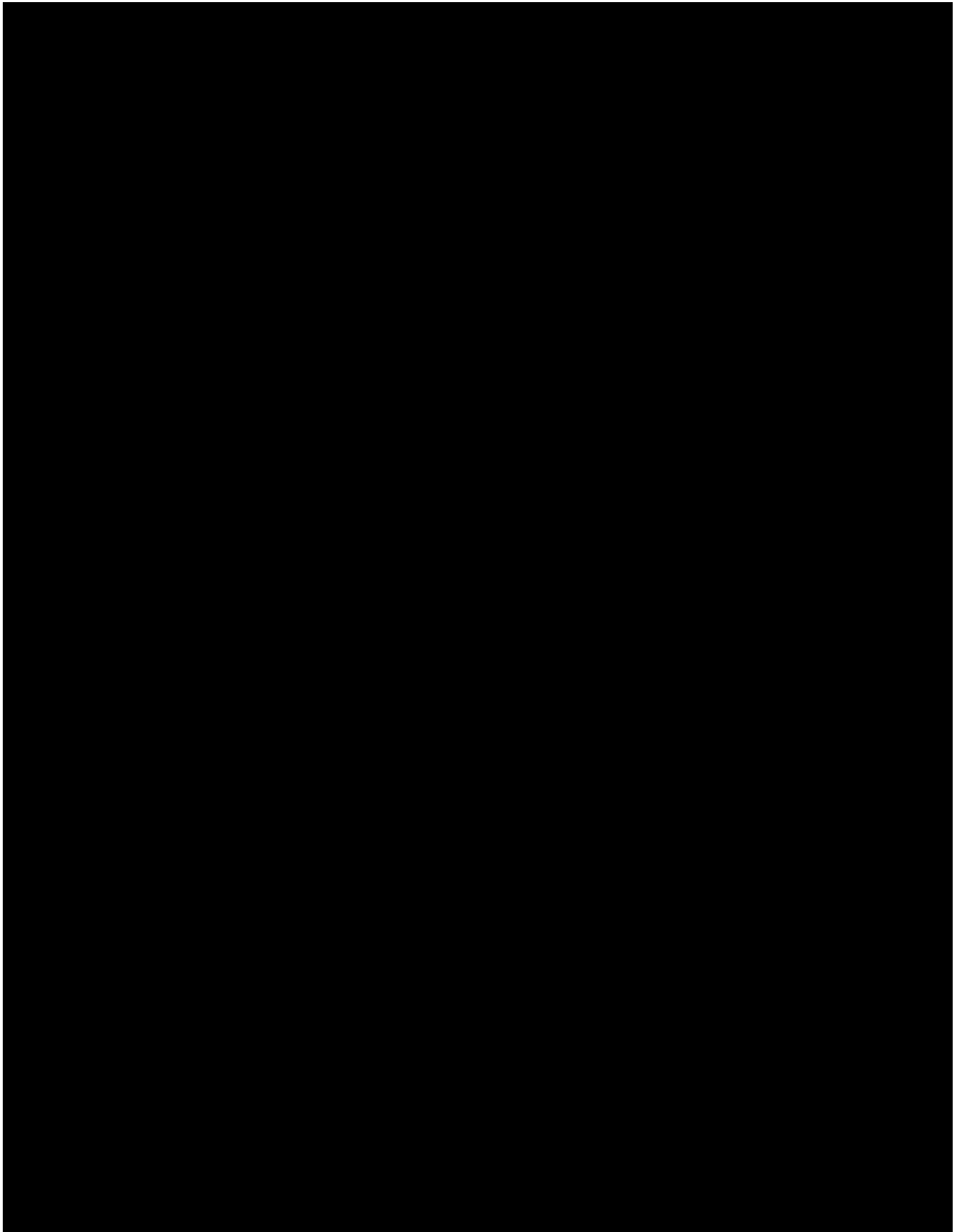


EXHIBIT 2

ATTACHMENT A

CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER

Attachment A - Infringement of U.S. Patent No. 9,855,001

This chart applies the claims of Magnolia's U.S. Patent No. 9,855,001 ("the '001 patent") against Kurin's blood culture collection sets numbered K-11221, K-11223, K-11225, D-11221, D-21223, D-11223, M-11221, M-21223, M-11223, M-21223, T-11221, T-21221, T-11223, T-21223, D-PIV12, D-PIV18, M-PIV12, M-PIV18, T-PIV12, T-PIV18, S-PIV4, and S-PIV10, (collectively, "the Accused Products").¹

Based on the information Kurin has provided to date, it is Magnolia's understanding that Accused Products K-11221, K-11223, K-11225 are models submitted to the FDA for approval. March 22, 2016 Email Re Kurin Numbering System [KUR-MAG-DE294038]. It is also Magnolia's understanding that one or more of these "K" versions of the Kurin Lock did not include the umbrella valve that is present in the Kurin Lock device that is commercially available today, however, in all other respects those earlier "K" versions that did not include the umbrella valve were the same or substantially similar to the current, commercially available Kurin Lock device.

The Accused Products are substantially similar to one another. D.I. 59 at 4 (Kurin stating that "Magnolia asserted 82 claims – later reduced to 44 – targeting a single Kurin device."). Each of the Accused Products includes a Kurin Lock device. *See, e.g.*, MAG-DE0000688–693 (<https://www.kurin.com/skin-contaminant-diversion/>) at 688 ("The Kurin Lock® - Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful specimen diversion device that automates diversion during the routine process of drawing a blood culture."). Kurin's website includes a "How it Works" page that includes a single animation that purports to describe and depict the operation of the Kurin Blood Collection Set that includes the Kurin Lock device. (<https://www.kurin.com/skin-contaminant-discard/>). The listing of Accused Products is intended to be a list of all commercially available versions of Kurin's blood culture collection sets.

Based on the information presently available to Magnolia, the Kurin Lock device consists of five (5) individual parts. *See* Dkt. 94, Declaration of Jonathan Hangartner in Support of Kurin's Samples of the Accused Product; 2020-07-01 Motion for Leave Hearing Transcript. As described in the Hangartner Declaration, those five components are a top plate, a bottom plate, a cap, an umbrella valve and a porous plug. *Id.* *See also* Kurin Drawing Numbers KUR-2005 (Top Housing) [KUR-MAG-DE001623-24], KUR-2006 (Bottom Housing) [KUR-MAG-DE001625-26], KUR-2007 (Cap) [KUR-MAG-DE001627], KUR-6010 (Hydrophobic Self-Sealing Plug) [KUR-MAG-DE001655], KUR-6011 (Umbrella Valve) [KUR-MAG-DE001656], and KUR-8036 (Assembly) [KUR-MAG-DE001659], MiniValve Part Number UM 053.002 SD (Umbrella Valve and seating suggestion) [KUR-MAG-DE003703];

¹ To the extent Kurin is selling other blood culture collection sets that use the Kurin Lock device, Magnolia accuses those versions as well and the analysis in this chart applies to those versions.

Attachment A

Manufacturing Procedure MP-016 [KUR-MAG-DE000104-124] and the duplicates of these drawings produced throughout KUR-MAG-DE000138-2362. A table (shown below) produced along with Kurin's engineering drawings shows that the same set of engineering drawings is for the Kurin Lock device found in every version of the Accused Product:

top level	D-11221	D-11223	D-21221	D-21223	D-PIV12	D-PIV18	M-11221	M-11223	M-21221	M-21223	M-PIV12	M-PIV18	T-11221	T-11223	T-21221	T-21223	T-PIV12	T-PIV18	S-PIV10	S-PIV18
IFU	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4000	KUR-4000	KUR-4000	KUR-4000	KUR-4029	KUR-4071	KUR-4090	KUR-4091
inner box label	KUR-4009	KUR-4010	KUR-4018	KUR-4021	KUR-4039	KUR-4076	KUR-4011	KUR-4017	KUR-4024	KUR-4072	KUR-4047	KUR-4042	KUR-4079	KUR-4084	KUR-4052	KUR-4058	KUR-4049	KUR-4082	KUR-4085	KUR-4088
shipper box label	KUR-4013	KUR-4014	KUR-4001	KUR-4022	KUR-4040	KUR-4077	KUR-4015	KUR-4016	KUR-4025	KUR-4028	KUR-4043	KUR-4040	KUR-4050	KUR-4050	KUR-4053	KUR-4056	KUR-4047	KUR-4083	KUR-4086	KUR-4089
tape	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003	KUR-5003
inner carton	KUR-5023	KUR-5023	KUR-5023	KUR-5023	KUR-5023	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5021	KUR-5023	KUR-5021	KUR-5040	KUR-5040
shipper box	KUR-5024	KUR-5024	KUR-5024	KUR-5024	KUR-5024	KUR-5021	KUR-5022	KUR-5022	KUR-5022	KUR-5022	KUR-5022	KUR-5022	KUR-5024	KUR-5024	KUR-5024	KUR-5024	KUR-5024	KUR-5022	KUR-5040	KUR-5041
label	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031	KUR-5031
packaged device	KUR-6002	KUR-6023	KUR-6024	KUR-6025	KUR-6028	KUR-6038	KUR-6020	KUR-6021	KUR-6026	KUR-6027	KUR-6029	KUR-6037	KUR-6031	KUR-6031	KUR-6031	KUR-6031	KUR-6031	KUR-6031	KUR-6040	KUR-6041
adhesive	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001	KUR-6001
prod label	KUR-6005	KUR-6006	KUR-6017	KUR-6020	KUR-6038	KUR-6071	KUR-6007	KUR-6007	KUR-6008	KUR-6017	KUR-6041	KUR-6047	KUR-6048	KUR-6051	KUR-6051	KUR-6051	KUR-6045	KUR-6041	KUR-6084	KUR-6087
tray/pouch	KUR-5015	KUR-5015	KUR-5015	KUR-5015	KUR-5015	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5017	KUR-5015	KUR-5015	KUR-5015	KUR-5015	KUR-5017	KUR-6084	KUR-6087
lid stock	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5018	KUR-5016	KUR-5016	KUR-5016	KUR-5016	KUR-5018	KUR-5037 (label st)	KUR-5037 (label st)
collection adapter	KUR-6006	KUR-6006	KUR-6006	KUR-6006	KUR-6006	KUR-6006	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6005	KUR-6024	KUR-6024	KUR-6024	KUR-6024	KUR-6024	KUR-6024	KUR-6024
collection set	KUR-6008	KUR-6009	KUR-6012	KUR-6013					KUR-6012	KUR-6013			KUR-6008	KUR-6009	KUR-6012	KUR-6013				
luer adapter					KUR-6007	KUR-6007					KUR-6007	KUR-6007								
male luer					KUR-6020	KUR-6020					KUR-6020	KUR-6020					KUR-6020	KUR-6020	KUR-6020	KUR-6020
female luer					KUR-6021	KUR-6021					KUR-6021	KUR-6021					KUR-6021	KUR-6021	KUR-6021	KUR-6021
vented cap for male luer					KUR-6022						KUR-6022						KUR-6022		KUR-6022	
tubing					KUR-6023-1	KUR-6023-1					KUR-6023-1	KUR-6023-1					KUR-6023-1	KUR-6023-1	KUR-6023-1	KUR-6023-1
extension set					KUR-6023-9	KUR-6023-9					KUR-6023-9	KUR-6023-9					KUR-6023-9			
cap for female luer						KUR-6025						KUR-6025						KUR-6025		
lock	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036	KUR-6036
top housing	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005	KUR-2005
btm housing	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006	KUR-2006
cap	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007	KUR-3007
adhesive	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000	KUR-3000
lubricant	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002	KUR-3002
plug	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010	KUR-6010
valve	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011	KUR-6011

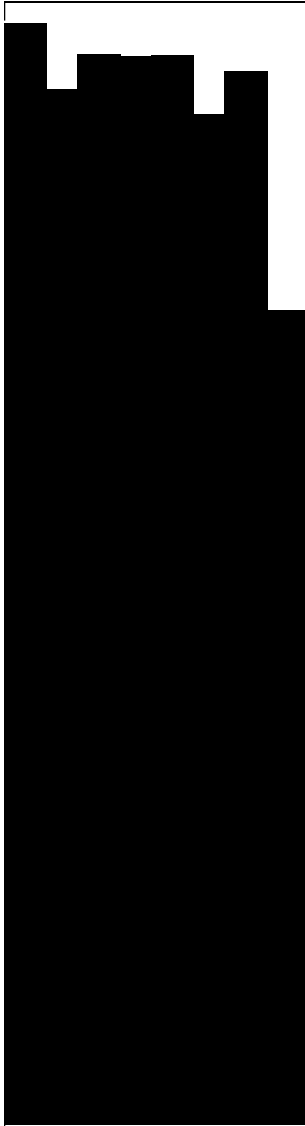
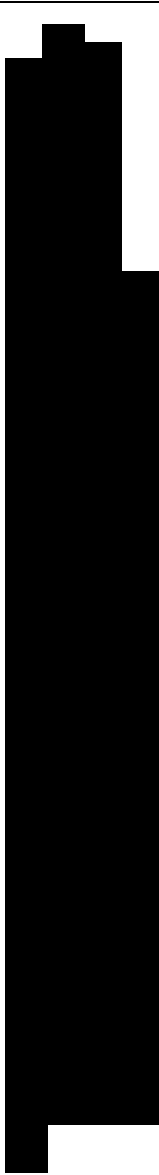

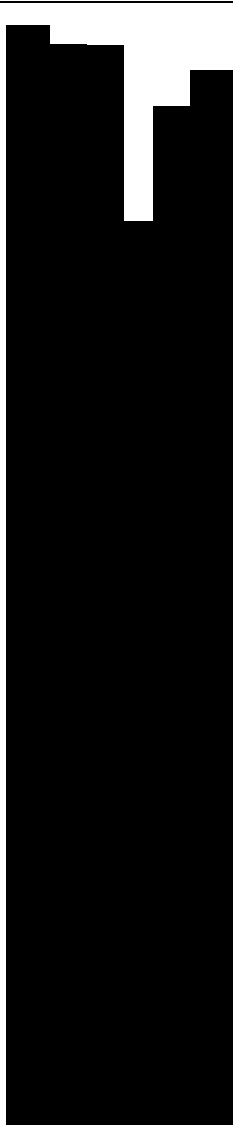

KUR-MAG-DE0001621 (boxed to show the Kurin Lock device schematics are the same for all Accused Products).

As such, Magnolia contends that, for purposes of the infringement analysis, the Accused Products are identical except where otherwise indicated below. Magnolia reserves its right to amend these contentions as additional information becomes available.

In addition to the exemplary documents provided in the chart, Magnolia also relies on and/or reserves the right to rely on the 510(k) submissions for the Accused Products produced by Kurin at KUR-MAG-DE000137 through KUR-MAG-DE0001620, the engineering drawings for the Accused Products produced by Kurin at KUR-MAG-DE0001621 through KUR-MAG-DE0001869, and Kurin's patent applications describing the Accused Products, including U.S. Patent Appl. Pub. 2018/0271425 [MAG-DEL0000720].

Claim 1	Accused Products
1. An apparatus for obtaining a bodily fluid sample from a	Each of the Accused Products is an apparatus for obtaining a bodily fluid sample from a patient with reduced contamination. <i>See, e.g.,</i>

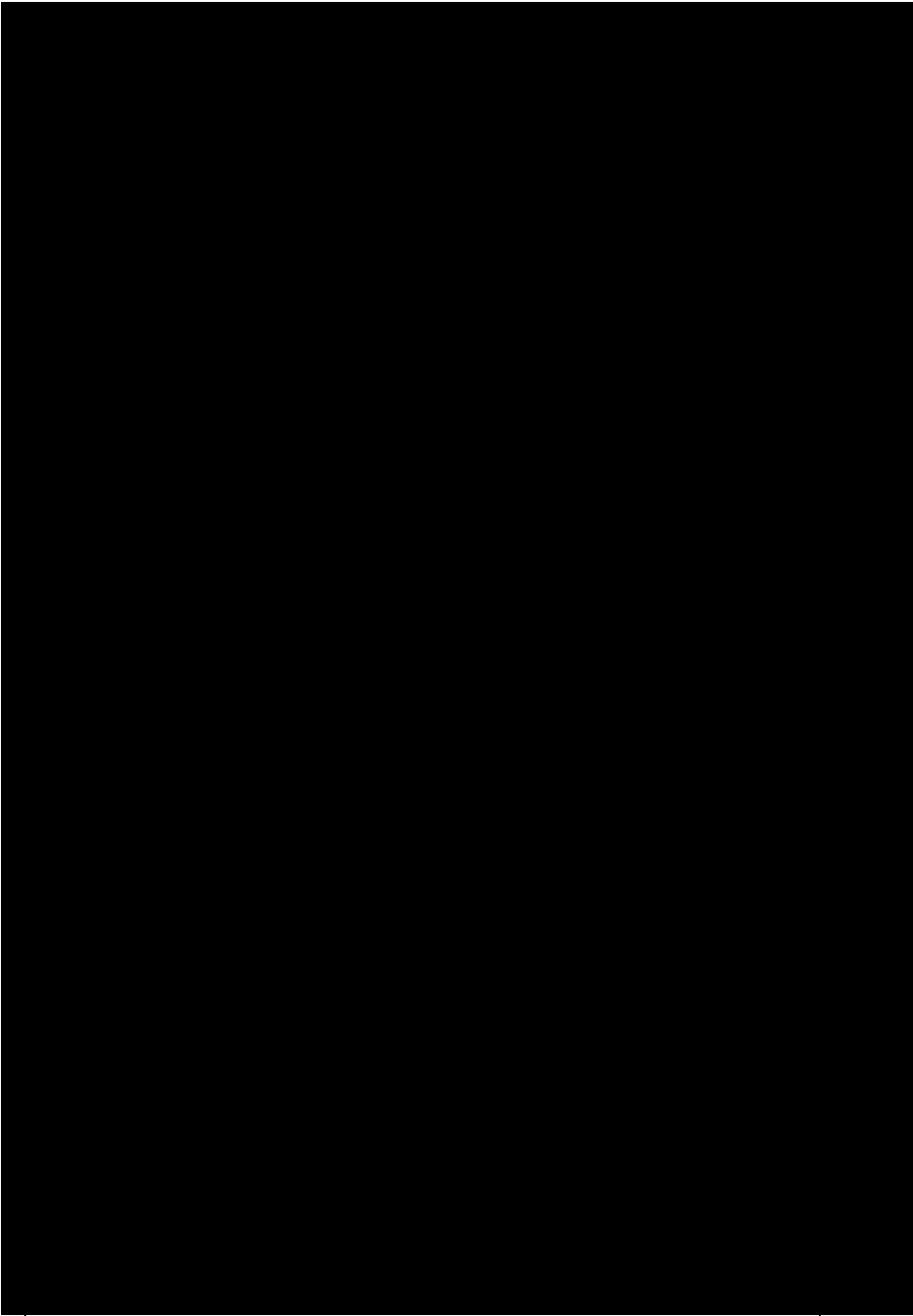
Attachment A

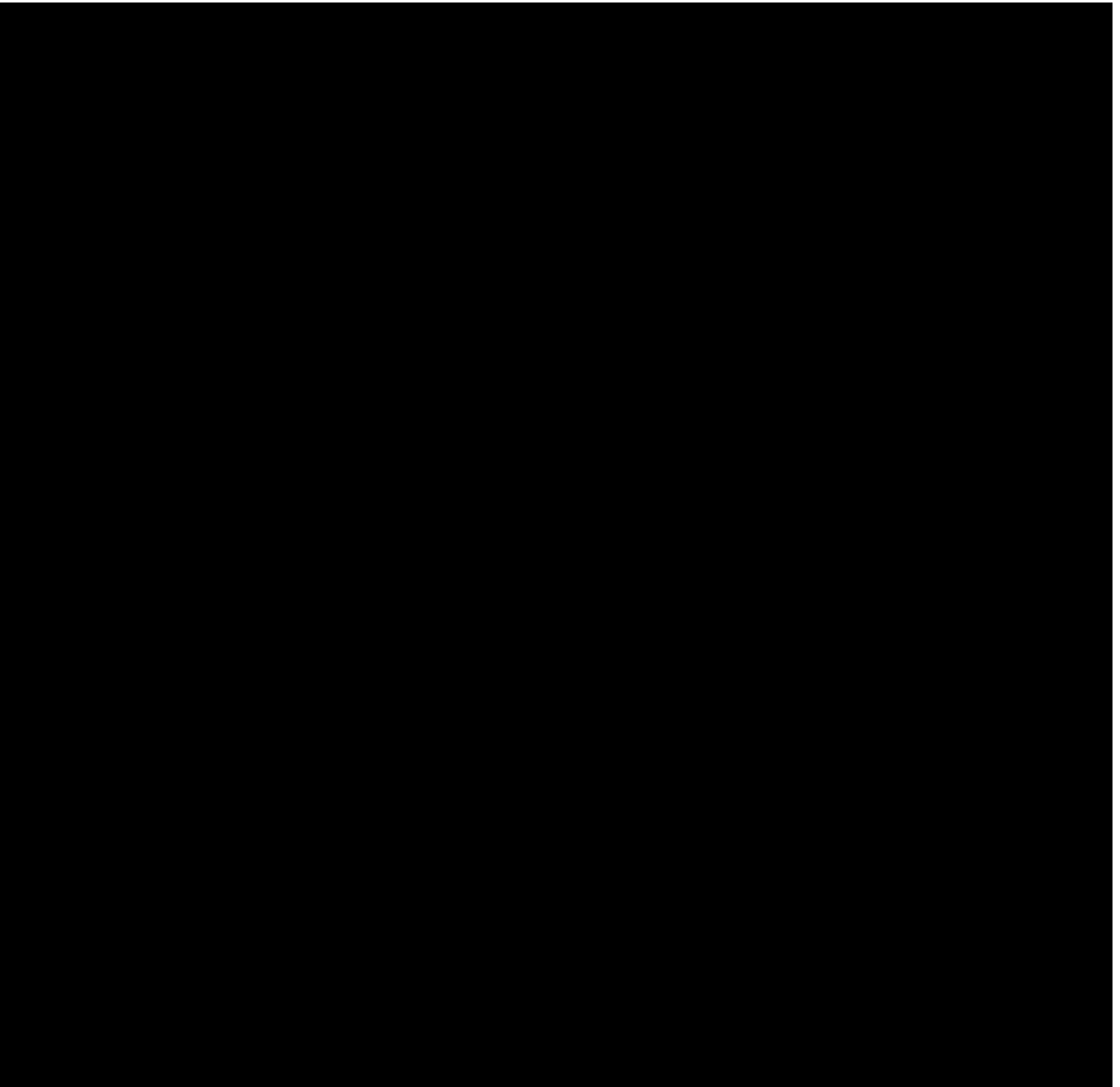
Attachment A

<div data-bbox="186 224 306 1306" data-label="Text"><p>[REDACTED]</p></div> <div data-bbox="332 214 634 1449" data-label="Text"><p>[REDACTED]</p></div>	<div data-bbox="673 224 703 1449" data-label="Text"><p>[REDACTED]</p></div> <div data-bbox="735 214 1182 1449" data-label="Text"><p>[REDACTED]</p></div>	<div data-bbox="1211 224 1403 1449" data-label="Text"><p>[REDACTED]</p></div>
<div data-bbox="186 1449 1211 1904" data-label="Text"><p>[REDACTED]</p></div>	<div data-bbox="1211 1449 1403 1904" data-label="Text"><p>[REDACTED]</p></div>	

Attachment A



Attachment A



CONFIDENTIAL – PURSUANT TO PROTECTIVE ORDER

Attachment A

<div>[REDACTED]</div>	<div>[REDACTED]</div>	<div>[REDACTED]</div>	<div>[REDACTED]</div>
<div>[REDACTED]</div>	<div>[REDACTED]</div>	<div>[REDACTED]</div>	<div>[REDACTED]</div>

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 19-97-CFC (CJB)

EXHIBIT 19

**MAGNOLIA’S OPPOSITION TO KURIN’S MOTION *IN LIMINE* NO. 3:
TO EXCLUDE EVIDENCE OR ARGUMENT THAT
KURIN’S WORD CHOICE IN MARKETING OR REGULATORY
DOCUMENTS IS EVIDENCE OF INFRINGEMENT**

Kurin seeks to exclude its own “FDA or marketing documents, emails, or other materials” that describe its accused product simply because they are inconsistent with the non-infringement arguments it now makes. It cannot do so.

Courts routinely consider a defendant’s descriptions of its product when assessing infringement. *See Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1320–21 (Fed. Cir. 2014) (finding that defendant’s “technical design documents[,] internal technical presentations[,] . . . planning documents, internal emails, and presentations” constituted substantial evidence of infringement); *SRI Int’l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1329 (Fed. Cir. 2021) (considering defendant’s internal documents as evidence of infringement); *AFG Indus., Inc. v. Cardinal IG Co.*, 375 F.3d 1367, 1373 (Fed. Cir. 2004) (same). Such evidence may include statements to the FDA, since there is no reason why “a fact finder should ignore a party’s representation to a federal regulatory body that is directly on point.” *Intendis GMBH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1362 (Fed. Cir. 2016); *see also Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1385 (Fed. Cir. 2009).

During this litigation, Kurin has made numerous claims about the accused Kurin Lock that are inconsistent with its prior descriptions of the device. For example, Kurin now asserts that “there is no evidence that the Kurin Lock ‘sequesters’ blood or contaminants.” D.I. 309 at 1. But Kurin repeatedly

represented to the FDA and its customers that the Kurin Lock “sequesters the initial draw of blood,” Ex. 19.A (MAG-DEL0000663) at -666, and [REDACTED] [REDACTED] Ex. 19.B (KUR-MAG-DE424575) at -575. It is proper for Magnolia and its expert, Dr. Santiago, to use such evidence to corroborate Dr. Santiago’s testing showing sequestration and his conclusions regarding infringement. *See nCube Corp. v. Seachange Int’l, Inc.*, 436 F.3d 1317, 1323 (Fed. Cir. 2006) (noting that plaintiff’s expert “supported his opinion by relying on [defendant’s] own technical documents”). Indeed, the Federal Circuit has affirmed attorneys’ fees where a defendant, among other things, “present[ed] weak non-infringement theories that were contrary to . . . [its] own internal documents.” *SRI Int’l*, 14 F.4th at 1332.

Kurin argues that its documents do not use the claim terms consistently with the Court’s constructions but tellingly does not discuss the constructions themselves. The Court held that the term “sequester” should be given its plain and ordinary meaning and rejected Kurin’s request for another construction. Ex. 19.C (Claim Construction Hr’g Tr.) at 19:1–20:1, Apr. 5, 2020. Accordingly, Kurin’s use of the word “sequester” in communications with the FDA and clinicians who use the product is directly relevant. Similarly, although the Court construed “diverter” in the ’001 Patent to be a means-plus-function term, the function it assigned is “to divert (or direct) fluid flow.” D.I. 75 at 2. The claims also use

“divert” independently of “diverter.” ’001 Patent at 13:19. Kurin’s documents that state that the Kurin Lock “automatically diverts the initial aliquot of blood,” *e.g.*, Ex. 19.D (MAG-DEL0000680) at -680, are thus probative of that function.

Kurin does not cite a single case excluding a defendant’s descriptions of its own product.¹ Kurin also fails to cite a case to support its suggestion that evidence from public documents predating the filing of the asserted claims is somehow improper because Magnolia could have referred to those documents in drafting the claims. There is no prohibition on drafting claims to exclude a competitor’s product. *See, e.g., Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988); *see also* Ex. 15 (Magnolia’s Mot. Lim. No. 2). In any event, the priority applications disclosing diverting and sequestering long predate Kurin’s product, as do claims in predecessor patents reciting those concepts. *E.g.*, U.S. Patent No. 8,864,684 cls. 9, 12 (divert); No. 8,231,546 cls. 13, 25 (sequester).

Kurin’s descriptions of its own product are highly probative of how that product functions and the Court should therefore deny Kurin’s Motion *in Limine*.

¹ *Ferring Pharms. Inc. v. Par Pharm., Inc.* found after trial that significant evidence contradicted descriptions in defendant’s documents. 267 F. Supp. 3d 501, 507 (D. Del. 2017). *Plastic Omnium* and *Intel Corp.* considered defendant’s documents and concluded that they used claim terms in a manner inconsistent with their express constructions, which were different than their plain and ordinary meanings. *See Plastic Omnium Advanced Innovation & Rsch. v. Donghee Am., Inc.*, 943 F.3d 929, 936 (Fed. Cir. 2019); *Intel Corp. v. Tela Innovations, Inc.*, No. 3:18-cv-02848-WHO, 2021 WL 1222622, at *5 (N.D. Cal. Feb. 11, 2021).

EXHIBIT 19.A



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2016

Pathway LLC.
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street North West
Buffalo, MN 55313

Re: K162233

Trade/Device Name: Kurin Blood Culture Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Set
Regulatory Class: Class II
Product Code: JKA
Dated: December 1, 2016
Received: December 8, 2016

Dear Mr. Mark Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 – Mr. Mark Job

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.**Indications for Use**510(k) Number (if known)
K162233Device Name
Kurin Blood Culture Collection Set**Indications for Use (Describe)**

The Kurin Blood Culture Collection Set is a winged blood collection needle with flexible tubing intended for venipuncture to obtain blood samples. It is provided with a safety shield for covering the used venipuncture needle prior to disposal to aid in the prevention of needlestick injury if manually activated after the blood draw. For blood collection, the set also includes a safety shield and apparatus for connection to vacuum based collection vials.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)☐ Over-The-Counter Use (21 CFR 801 Subpart C)**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

- A. Submitter:** Pathway LLC, on behalf of Calliope Solutions, Inc.
- B. Date Prepared:** September 7, 2016
- C. Address:** 8779 Cottonwood Ave, Suite 105, Santee CA 92071
- D. Corporate Contact:** David Stroup
- E. Submission Contact:** Emily Davis, Quality Consultant
Pathway LLC
8779 Cottonwood Ave
Suite 105
Santee CA 92071
Ph: 949.636.4621
Email: erbakersd@gmail.com
- F. Trade Name:** Kurin Blood Culture Collection Set
- G. Predicate Device(s):** (1) BD Vacutainer Blood collection set and Safety-Lok blood collection set (K980414)
(2) Smith Medical Saf-T Holder Adapter (K923090)
- H. Common Name:** Venous Blood Collection Device
- I. Classification:** Class II

Regulation Number	Product Code	Classification Name	Device Class
862.1675	JKA	Blood Specimen Collection Device	II

J. Device Description

The Kurin device is a sterile, single use blood culture collection set. The Kurin includes a winged needle with flexible tubing and an attached vial adapter intended for venipuncture to obtain blood culture samples. Kurin is identical in every way to existing sets used to collect blood culture samples except for the insertion into the tubing of the Kurin blood capture chamber. The Kurin blood capture device sequesters the initial draw of blood upon initial venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal. The amount of blood diverted is very small, estimated at a fraction of 1 ml.

Below is a table with the three models and sizes of the subject device's that intend to be marketed.

Model	Measurement (mm)			Weight (g)	Tubing	Gauge
	H	D	W			
K-11221	31mm	13mm	6.45mm	15.7g	12 in	21 Gauge
K-11223	31mm	13mm	6.45mm	15.7g	12 in	23 Gauge
K-11225	31mm	13mm	6.45mm	15.7g	12 in	25 Gauge

K. Intended Use

The Kurin Blood Culture Collection Set is a winged blood collection needle with flexible tubing intended for venipuncture to obtain blood samples. It is provided with a safety shield for covering the used

venipuncture needle prior to disposal to aid in the prevention of needlestick injury if manually activated after the blood draw. For blood collection, the set also includes a safety shield and apparatus for connection to vacuum based collection vials.

L. Predicate Device(s)

The Kurin device is substantially equivalent to the following FDA cleared predicate devices:

Predicate #1

510(k) Number: K980414
 Trade Name: Vacutainer Brand Safety-Lok Blood Collection Set
 Model Multiple
 Manufacturer: **Becton Dickinson**
 Common/Usual Name: Accessory to: Tubes, Vials, Systems, Serum
 Separators, Blood Collection
 Regulation Number: 862.1675
 Product Codes: JKA
 Classification: II

Predicate #2

510(k) Number: K923090
 Trade Name: Saf-T Holder Multi Sample Luer Adapter
 Manufacturer: **Smiths Medical**
 Common/Usual Name: Tubes, Vials, Systems, Serum Separators, Blood
 Collection
 Regulation Number: 862.1675
 Product Codes: JKA
 Classification: II

M. Substantial Equivalence

Feature	Proposed Device The "Kurin"	VACUTAINER BRAND SAFETY-LOK BLOOD COLLECTION SET MODEL MULTIPLE K980414	SAF-T HOLDER MULTI SAMPLE LUER ADAPTER W/ BLOOD K923090
Indications for Use	The Kurin Blood Culture Collection Set is a winged blood collection needle with flexible tubing intended for venipuncture to obtain blood samples. It is provided with a safety shield for covering the used venipuncture needle prior to disposal to aid in the prevention of needlestick injury if manually activated after the blood draw. For blood collection, the set also includes a safety shield and apparatus for connection to vacuum based collection vials.	The VACUTAINER® brand blood collection sets and Safety-Lok™ blood collection set is a winged blood collection needle and flexible tubing for venipuncture to collect blood specimens from patients or monitoring blood pressure. The Safety-Lok™ blood collection set also contains a needle safety shield which minimizes the possibility of needlesticks if manually activated following blood collection. The VACUTAINER® brand blood collection sets and Safety-Lok™ blood collection set is also recommended for use in patients with small veins. The VACUTAINER® brand blood collection sets and Safety-Lok™ blood collection set is also indicated for the intravenous administration of fluids and may be used for any patient	The Saf-T HOLDER® Blood Culture device is intended for use as a culture bottle or vacuum tube holder that can be attached to a female Luer connector of the Saf-T Wing® blood collection set or equivalent.

		population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy.	
Device Description	The Kurin set is a sterile, single use blood culture collection set. The Kurin includes a winged needle with flexible tubing and an attached vial adapter intended for venipuncture to obtain blood culture samples. Kurin is identical in every way to existing sets used to collect blood culture sample except for the insertion into the tubing of the Kurin blood capture chamber. The Kurin blood capture device sequesters the initial draw of blood upon initial venipuncture. The set is provided with a safety shield for covering the used needle prior to disposal. The amount of blood diverted is very small, estimated at a fraction of 1 ml.	The Vacutainer Brand Blood Collection sets and safety-Lok blood collection set is a sterile winged blood collection needles with flexible tubing and a female luer adapter manufactured by Becton Dickinson Vacutainer Systems, Sumter, South Carolina. The Safety-Lok Blood Collection set is provided with a safety shield for covering the used needle prior to disposal. A male luer adapter is provided on specific reorder numbers. A male luer adapter contains a non-patient needle end for puncturing the stopper of an evacuated blood collection tube. Those without a male luer adapter are provided a protective cap on the end of the female luer adapter.	The Saf-T HOLDER® Blood Culture device is a sterile multi-sample luer adapter for venous blood sampling that includes a blood culture bottle holder with a fixed back end needle, male luer threaded connector and vacuum tube adapter.
Product Code	JKA	JKA	JKA
Patient Interface	Used only by trained professionals in a medical setting	Used only by trained professionals in a medical setting	Used only by trained professionals in a medical setting
Materials and Chemical Composition			
Kurin Materials	Makrolon Polycarbonate	unknown, medical grade plastic	unknown, medical grade plastic
Tubing	Transparent Flexible tubing	Substantially equivalent	NA since this is just the adapter
Adapter	Male or Female Luer	Substantially equivalent	Substantially equivalent
Performance/Design Specifications			
Sequesters initial blood	Yes	No	No
Single Use Device	Single Use	Single Use	Single Use
Indicated for Infusion	No	Yes	No
Needle Gauge	21, 23, 25 Gauge	21, 23, 25 Gauge	Standard vial adapter
Labeled Pyrogen Free	No	Yes	No
Sterilization	Yes, EtO	Yes, EtO	Yes, EtO

Expiration/Shelf Life	1 year (with protocols up to 3 years)	3 years	5 years
Size (LxWxH)	21G, 3/4 inch, 12 inch tubing,0.337 volume 23G, 3/4 inch, 12 inch tubing,0.332 volume 25G, 3/4 inch, 12 inch tubing,0.331 volume	21G, 3/4 inch, 12 inch tubing,0.337 volume 23G, 3/4 inch, 12 inch tubing,0.332 volume 25G, 3/4 inch, 12 inch tubing,0.331 volume	2.5 in x 2 in
Principles of Operation	The winged needle is used to access the patient's blood stream, the safety shield is used cover the needle after collection, the kurin component sequesters the initial sample of blood and the vial adapter is used to interface with a vacuum tube or culture bottle. There is no energy source, the subject device fills with blood by differences in pressure gradient.	The winged needle is used to access the patient's blood stream, the safety shield is used cover the needle after collection, the tubing and luer connector are used to attach to a vial adapter or infusion set. There is no energy source, the subject device fills with blood by differences in pressure gradient.	Cylindrical holder for vacuum bottle or tube placement with threads that are compatible with blood collection needles and luers.
Biocompatibility	Conforms with ISO 10993	Conforms with ISO 10993	Conforms with ISO 10993

N. Non-Clinical Testing

All testing met specifications for the subject device and demonstrates substantial equivalence to the predicates.

1. Sterilization – The Kurin device is sterilized using a validated EO sterilization process which complies with ISO 11135-1:2006 Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
2. Aging/Shelf Life Test– The Kurin device was validated to achieve 1-year shelf life with protocols for up to 3 years of shelf life for sterility and performance.
3. Functional, Leakage and Tensile Test – The Kurin set confirmed the addition of the Kurin device shows no compromise to the function of the blood collection device in regards to functionality. With the addition of the device the product does not leak and passed tensile testing in accordance with sections 5.2 and 5.3 of ISO 1135-3 - Transfusion equipment for medical use -- Part 3: Blood-taking set for single use.
4. Packaging Integrity and Shipping Test – This test was completed and the Kurin device passed all tests in accordance with ISO 11607 and ASTM D4169-14.
5. Biocompatibility Tests – The Kurin device passed two types of biocompatibility tests: the MEM Elution Test demonstrated that no leachables are present from the system and the IVH Blood Count Test which demonstrated that the blood path did not adversely affect the constituents of blood exposed to the systems fluid path.
6. User Verification Test - Testing was conducted to evaluate if the instructions for use were easy to understand and the functionality of the device.
7. Flow Rate Test – Testing verified that the addition of the Kurin Device into the tubing of the FDA cleared BD Vacutainer® brand blood collection set and Safety-Lok™ Blood Collection set did not change the flow rate of liquid passing through the device.

O. Clinical Testing

No clinical test data is required of the Proposed Device.

P. Conclusion

The above information and tests conducted demonstrate that the Subject Device is substantially equivalent to the identified predicates.

EXHIBIT 19.B

FILED UNDER SEAL

EXHIBIT 19.C

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

MAGNOLIA MEDICAL : CIVIL ACTION
TECHNOLOGIES, INC., :
 :
Plaintiff, :
 :
 :
vs. :
 :
 :
KURIN, INC., :
 :
 :
Defendant. : NO. 19-00097-CFC

- - -

Wilmington, Delaware
Wednesday, April 15, 2020
9:15 o'clock, a.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

FISH & RICHARDSON P.C.
BY: DOUGLAS E. McCANN, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

1 APPEARANCES (Continued) :

2
3 FISH & RICHARDSON P.C.
4 BY: MATHIAS W. SAMUEL, ESQ.

5 -and-

6 FISH & RICHARDSON P.C.
7 BY: CORRIN N. DRAKULICH, ESQ.
8 (Atlanta, Georgia)

9 -and-

10 FISH & RICHARDSON P.C.
11 BY: JUANITA R. BROOKS, ESQ.
12 (San Diego, California)

13 -and-

14 FISH & RICHARDSON P.C.
15 BY: JAMES HUGENINE-LOVE, ESQ.
16 (Minneapolis, Minnesota).

17 Counsel for Plaintiff

18 MORRIS JAMES LLP
19 BY: KENNETH L. DORSNEY, ESQ. and
20 CORTLAN S. HITCH, ESQ.

21 -and-

22
23
24
25

1 APPEARANCES (Continued) :

2
3 TURNER BOYD LLP
4 BY: KAREN I. BOYD, ESQ. and
5 JACOB ZWEIG, ESQ.
(Redwood City, California)

6 -and-

7 X-PATENTS, APC
8 BY: JONATHAN HANGARTNER, ESQ.
9 (La Jolla, California)

10 Counsel for Defendant

11 - - -
12
13
14
15
16
17
18
19
20
21
22
23
24
25

1 component for mechanism. Again, if this is found not to be
2 a means-plus-function, then we wouldn't -- you know, we
3 believe that's an appropriate construction.

4 The difference on impact, of course, is
5 restriction specifically to the disclosed structures to
6 perform the function that's claimed, and so the result would
7 be a more narrow reading of the patents just to require one
8 of those two structures or their substantial equivalent to
9 be found in the accused device versus this broader
10 construction, which would allow for other types of
11 mechanisms beyond the two specific structures that were
12 disclosed in the patent.

13 THE COURT: Right. I see. Well, you know what.
14 I read MTD the way I do, so I do think it's a
15 means-plus-function limitation, and so what I'm going to do
16 is, I will give plaintiffs a week to in a letter propose
17 what they think is the structure that's disclosed in the
18 written description to the extent it differs from what the
19 defendants have said, and I will receive that. That letter
20 should be no more than 750 words in 14-point font, and
21 defendants will have a week to reply to that letter with a
22 750 word letter. All right? So that's how we're going to
23 leave that then unresolved. I am finding I think under MTD,
24 means-plus-function applies for the reasons I've articulated
25 on the record.

1 All right. So then let's go back. Let's start
2 with sequester. And I asked defendants in my oral order
3 yesterday about how does isolate differ. I mean, as far as
4 I'm concerned, you have basically conceded in your brief
5 that the two terms are synonymous and that really the only
6 justification for your argument is that you believe that
7 isolate is more readily understandable by a jury.

8 Am I fairly characterizing your position,
9 defendant?

10 MS. BOYD: Your Honor, this is Karen Boyd. I
11 will be speaking to that point.

12 Yes, I think that's a fair characterization. We
13 believe that sequester and isolate mean the same thing and
14 merely that isolate would be much easier for a jury to
15 understand and apply.

16 THE COURT: Okay. Thank you. And I'm going to
17 rule in plaintiff's favor on this. The argument, the
18 gravamen of defendant's argument I think is set forth on
19 page 22 of the joint brief, and as counsel just confirmed,
20 the two words are synonyms, they are equal in scope, and
21 just the defendant's position is that isolate is more easily
22 understood by a jury. I don't agree with that. I think
23 International Rectifier Corp. at 361 F3d. 1363 governs and
24 that the Federal Circuit has cautioned that we must consider
25 the word that the inventor actually chose and merely

1 rephrasing claim language is not claim construction.

2 All right. Let's go to the next term, initial
3 volume. Let me ask the plaintiff this. On page 30 of the
4 brief, the defendants say that the asserted patents use the
5 term initial volume, bodily fluid/blood, and this is the
6 important part, "To refer to the initial portion of blood
7 removed from the patient and sequestered so that a clean
8 blood sample can be taken."

9 Will the plaintiffs agree to that definition,
10 that construction of the term?

11 MS. BROOKS: Again, Your Honor, this is Juanita
12 Brooks speaking.

13 I would need to talk to the team about that.
14 Could Your Honor -- I'm sorry. Page 30 and defendant's
15 answering position.

16 THE COURT: Yes. I mean, the defendants say
17 that the term "refers to the initial portion of blood
18 removed from the patient sequestered so that a clean blood
19 sample can be taken."

20 I'm just wondering, would you just not agree to
21 that?

22 MS. BROOKS: I think that we might, Your Honor.
23 Could I have an opportunity? Could we defer this and I have
24 an opportunity to talk, communicate offline with the team to
25 make sure that one of my partners isn't about to come out of

EXHIBIT 19.D



kurin®

Blood Culture Collection Sets

Traditional blood culture collection methods provide skin microbes a direct line to the culture.

Kurin technology diverts the initial aliquot of blood which may contain skin contaminants. Roughly 20% of the microbes present in skin reside deep in the dermis.¹ With venipuncture, contaminants may be dislodged and drawn into blood culture samples leading to high rates of seemingly unavoidable false positives.

Standing guard between the venipuncture site and the culture bottle, the Kurin Lock® specimen diversion device corrals blood from the venipuncture site while the clinically relevant blood sample flows into the blood culture bottle.

Why Use It?

Approximately 1/3 of all positive blood cultures are false positive results due to blood culture contamination.

Hospitals spend \$4,500-\$10,000¹ per false positive test that leads to unnecessary treatment of non-existent bloodstream infections. There are high costs for patients as well. Extended hospital stays increase the risk of hospital-acquired infections and adverse events. Unnecessary antibiotics increase the risk of allergic reactions, drug interactions, and drug-resistant superbugs.

How does it work?

Each Kurin blood culture collection set features a Kurin Lock®, a small but powerful device that automatically diverts the initial aliquot of blood during the routine process of drawing a blood culture.



Serves as a flash chamber to provide visual confirmation of proper needle placement in the vein.




Any contaminants residing in the initial ~0.15ml volume of blood (35x a standard 21G needle) are captured in the u-shaped Kurin Lock®.



When the collection bottle is attached, blood flows directly from the vein into the culture bottle through a separate channel.

¹ Garcia RA, et al. Am J Infect Control. 2015 Nov 1;43(11):1222-37.

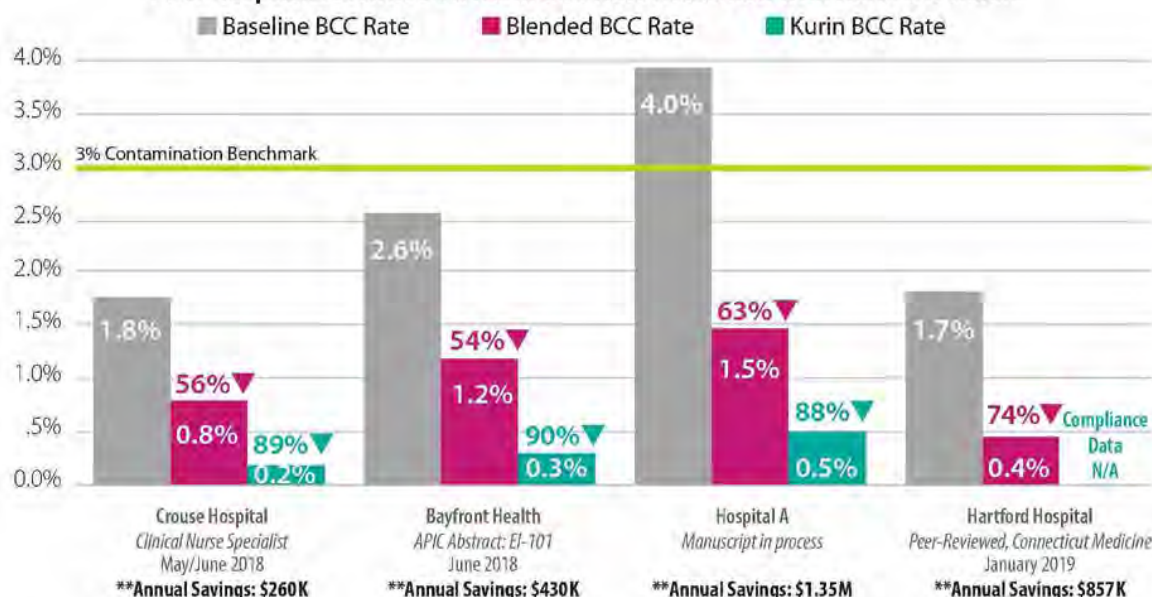


Reshaping Blood Culture Collection

Don't give contamination a pass — **STICK with Kurin®**

When Kurin was used, even hospitals below the 3% benchmark reduced blood culture contamination (BCC) rates by up to 90%* with significant cost savings.

Four Hospitals: Blended vs. Kurin BCC Rate Reduction with Kurin Diversion



* Fluctuations in caregiver compliance are reflected in the blended rates, while Kurin rates reflect the efficacy of Kurin when it was used.

** Annual savings are based on a cost of \$4500/BCC.

SIMPLE. PASSIVE. LOW WASTE. HIGH RETURN.

Kurin is the diversion solution designed for frontline clinicians.

- FDA 510(k) cleared
- Peer reviewed
- Automatic diversion
- Blood conserving for Peds
- Flash chamber
- Diversion for PIV draws
- Diversion for syringe draws
- Low waste packaging
- Supports antimicrobial stewardship



KURIN PRODUCT ORDERING: 200/SKU/ Case

To place an order, email orders@kurin.com, or fax a purchase order to: 1-858-228-5160.

Kurin for Direct Venipuncture						
	BD Bactec [®] and Thermo Fisher VersaTREK [®] REDOX [™] EZ DRAW [™]		bioMérieux BacT/Alert [®]		Thermo Fisher VersaTREK [™] REDOX [™]	
	21 Gauge	23 Gauge	21 Gauge	23 Gauge	21 Gauge	23 Gauge
Safety Slide Needles	D-11221	D-11223	M-11221	M-11223	T-11221	T-11223
Push Button Needles	D-21221	D-21223	M-21221	M-21223	T-21221	T-21223
Kurin for Peripheral IV Collection						
12-inch set	D-PIV12		M-PIV12		T-PIV12	
12-inch set + 6-inch extension	D-PIV18		M-PIV18		T-PIV18	
Kurin for Low-Volume Syringe Draws						
4-inch set	S-PIV4					
6-inch extension	S-PIV10					



Need additional information? Call our customer service team at 1-888-963-9056 or email cs@kurin.com.

Kurin, Inc. 10755 Scripps Poway Parkway, Suite 257 • San Diego, CA 92131 • Fax: 858.228.5160 • 888.963.9056
 Copyright © 2019 Kurin Inc. All rights reserved. Kurin® and Kurin Lock® are registered trademarks of Kurin, Inc. • ML-033_Rev E_0319
 FDA 510(k) Cleared. U.S. and foreign patents and patents pending • www.kurin.com/patents.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

v.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**KURIN’S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE* NO. 3
TO EXCLUDE EVIDENCE OR ARGUMENT THAT KURIN’S WORD
CHOICE IN MARKETING OR REGULATORY DOCUMENTS IS
EVIDENCE OF INFRINGEMENT**

RICHARDS, LAYTON & FINGER, P.A.
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

OF COUNSEL:
Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000

June 3, 2022

Magnolia does not dispute that the testing evidence both parties conducted is the most probative and direct evidence bearing on infringement. Or that where such more probative evidence exists, courts have repeatedly found a defendant's description of its accused products not probative of infringement, after that evidence was already admitted at trial. *See* MIL No. 3 at 2. Kurin seeks to prevent that outcome here, since admission of the prejudicial evidence at issue (which are not "technical documents") would lead to an unnecessary mini-trial about what parties previously believed instead of what the direct evidence now shows. Kurin would need to respond in kind by introducing mirroring indirect evidence, of Magnolia's own repeated historical assertions in court filings and marketplace communications that it does *not* believe the Kurin Lock's design "sequesters," and instead allows mixing. *See* Ex. 3 ¶ 106; Ex. 4. Kurin will also need to clarify for the jury that Magnolia drafted the claims at issue only after Kurin descriptions of the type at issue became publicly available. *See* Opp. to MMT MIL No. 2. None of Magnolia's cases involved admission of evidence that would thus necessarily inject a maelstrom of tangential issues likely to confuse the jury and waste time, including evidence Magnolia itself seeks to exclude *See* MMT MIL No. 2. Magnolia's attempts to distract the jury from the key evidence of how the Kurin Lock actually works should be rejected.

RICHARDS, LAYTON & FINGER,
P.A.

OF COUNSEL:

Nicholas Groombridge
Catherine Nyarady
Kripa Raman
Joshua D. Reich
Ariella Barel
PAUL, WEISS, RIFKIND, WHARTON &
GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000
ngroombridge@paulweiss.com
cnyarady@paulweiss.com
kraman@paulweiss.com
jreich@paulweiss.com
abarel@paulweiss.com

/s/ Kelly E. Farnan
Kelly E. Farnan (#4395)
Richards, Layton & Finger, P.A.
920 N. King Street
One Rodney Square
Wilmington, DE 19801
(302) 651-7700
Farnan@rlf.com

Attorneys for Defendant Kurin, Inc.

June 3, 2022

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

C.A. No. 1:19-cv-00097-CFC
(CJB)

**DECLARATION OF ARIELLA BAREL IN SUPPORT OF
KURIN, INC.'S REPLY IN SUPPORT OF ITS MOTION *IN LIMINE*
NO. 3 TO EXCLUDE EVIDENCE OR ARGUMENT THAT KURIN'S
WORD CHOICE IN MARKETING OR REGULATORY DOCUMENTS
IS EVIDENCE OF INFRINGEMENT**

I, Ariella Barel, declare as follows:

I am a member in good standing of the bar of the State of New York, First Department and am associated with Paul, Weiss, Rifkind, Wharton & Garrison LLP, counsel for Defendant Kurin, Inc. (“Kurin”) in this action. I have been admitted *pro hac vice* for this matter. I respectfully submit this Declaration in support of Kurin’s reply in support of its Motion *in Limine*, which is filed herewith.

1. Attached hereto as **Exhibit 3** is a true and correct copy of an excerpt of the Amended Answer and Counterclaims of Magnolia Medical Technologies, Inc. in Case No. 3:18-cv-01060-L-JMA, dated August 3, 2018.

2. Attached hereto as **Exhibit 4** is a true and correct copy of an email from Bob Gerberich with subject line “K Compare” and its attachment, a document titled “Steripath vs Kurin Lock Comparison MM00065 Rev C,” bearing Bates numbers MAG-DEL0014337–14339 and dated March 29, 2018.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on June 3, 2022.

/s/ Ariella Barel
Ariella Barel

EXHIBIT 3

CHRISTOPHER M. YOUNG (SBN 163319)
christopher.young@dlapiper.com
MELISSA A. REINCKENS (SBN 314657)
melissa.reinckens@dlapiper.com
DLA PIPER LLP (US)
401 B Street, Suite 1700
San Diego, CA 92101-4297
Tel: 619.699.2700
Fax: 619.699.2701

Attorneys for Defendant and
Counterclaimant
Magnolia Medical Technologies, Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

KURIN, INC.,

Plaintiff,

v.

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Defendant.

MAGNOLIA MEDICAL
TECHNOLOGIES, INC.,

Counterclaimant,

v.

KURIN, INC.,

Counterdefendant.

CASE NO. 3:18-cv-01060-L-JMA

**AMENDED ANSWER AND
COUNTERCLAIMS OF MAGNOLIA
MEDICAL TECHNOLOGIES, INC. TO
COMPLAINT FOR:**

**1. FALSE ADVERTISING
(LANHAM ACT)**

**2. VIOLATION OF B&P CODE
§ 17500, *et seq.***

DEMAND FOR JURY TRIAL

Courtroom: 5B (5th Flr - Schwartz)
Judge: Hon. M. James Lorenz

Defendant Magnolia Medical Technologies, Inc. ("Magnolia") hereby files
this Amended Answer to Plaintiff's Complaint:

1 positive blood cultures. This representation is intended to convey, and in fact
2 conveys, the false and/or misleading message that Kurin was the first blood culture
3 collection device in the market that reduces false positives in blood cultures testing.

4 102. Thus, despite (a) Magnolia's well-known Steripath® product being
5 introduced years before the Kurin Blood Culture Collection Set; and (b) two (2)
6 controlled clinical studies published in peer-reviewed journals and seven (7)
7 clinical abstracts accepted and presented at major medical conferences
8 demonstrating the clinical efficacy of the Steripath® product, Kurin has suggested
9 and continues to suggest to consumers through its advertising, including on its
10 website, that it was the *first* to market a blood culture collection set that reduces
11 false positive blood cultures. In doing so, Kurin is conveying false and/or
12 misleading representations to consumers.

13 103. Additionally, Kurin's "until now" claim also implies that Kurin is the
14 *only* provider of products capable of reducing false positive results, when it
15 knowingly is not.

16 104. Kurin's representation that "until now" with the introduction of the
17 Kurin Lock specimen diversion device, hospitals had to accept high rates of
18 seemingly unavoidable false positive blood cultures is false and/or misleading, and
19 has the potential to confuse consumers because it deprives consumers of accurate
20 information regarding Kurin's devices and others in the marketplace.

21 **KURIN MISREPRESENTS ITS PRODUCT'S CAPABILITIES**

22 105. Kurin misrepresents its product's capabilities in many places on its
23 website and otherwise.

24 106. Throughout its advertising, including on its website, Kurin represents
25 to consumers that "[e]ach Kurin blood culture collection set features a Kurin
26 Lock™, a small but powerful specimen diversion device that automates skin
27 contaminant diversion during the routine process of drawing a blood culture." In
28 addition, throughout its marketing campaign, including on its website, Kurin

1 repeatedly refers to its diversion technology as the Kurin Lock. Kurin also
2 represents to consumers on its website that the Kurin Lock “[s]tand[s] guard
3 between the venipuncture site and the culture bottle,” and explains that the “Kurin
4 Lock diverts the initial blood specimen that may contain skin microbes from deep
5 within the dermis. A clinically-relevant specimen then bypasses the contaminants
6 locked within the device.” Upon information and belief, Kurin Lock does not
7 contain a lock, physical barrier, or any other mechanical isolation capability. Upon
8 information and belief, contrary to its representations to consumers and brand
9 messaging, in Kurin’s device there is no lock that physically separates the
10 contaminants from the sample blood pathway. Accordingly, Kurin’s representations
11 to consumers that Kurin’s device contains a “lock” is false and/or misleading
12 because it implies that its blood collection set employs a physical barrier, when in
13 fact no such physical barrier exists.

14 107. Kurin also claims throughout its marketing that its product is “better.”
15 Because Magnolia invented and was the first to market a blood collection device -
16 Steripath® - with initial specimen diversion technology, Magnolia is the industry
17 pioneer. Magnolia’s technology is proven, and backed by nine published clinical
18 datasets. Kurin’s statements that it is “better” is intended to convey and in fact
19 conveys the false and/or misleading message to consumers that Kurin’s blood
20 collection set is better than Magnolia’s Steripath® devices.

21 108. Kurin further represents throughout its advertising that its blood
22 collection device is easy to use, or simple, when it is not. For example, Kurin’s
23 advertising and marketing uses the terms “seamless integration” and “effortless
24 passive compliance,” and defines those terms as meaning “no change in patient
25 experience or caregiver practice” and “without slowing down busy clinicians,”
26 respectively. However, upon information and belief, customers of Kurin’s products
27 have stated that—even after months of training— further training to become
28 familiar with its specific operation is still required to use the device properly.

1 reasonable attorneys' fees incurred in this action;

2 7. Magnolia requests that this Court enter such other relief as this Court
3 deems just and proper.

4 **JURY DEMAND**

5 Magnolia hereby requests a trial by jury on all of its counterclaims.

6
7 Dated: August 3, 2018

8 **DLA PIPER LLP (US)**

9
10 By /s/Christopher M. Young
11 CHRISTOPHER M. YOUNG
12 MELISSA A. REINCKENS
13 Attorneys for Defendant
14 Magnolia Medical Technologies, Inc.
15
16
17
18
19
20
21
22
23
24
25
26
27
28

CERTIFICATE OF SERVICE

I certify that on August 3, 2018, I caused a true and correct copy of:

AMENDED ANSWER AND COUNTERCLAIMS OF MAGNOLIA
MEDICAL TECHNOLOGIES, INC.

to be filed electronically with the Clerk of the Court through the CM/ECF System
which will send notification of such filing to the email addresses denoted in the
Electronic Mail Notice List appearing on Pacer, and I hereby certify that I have
mailed the aforementioned documents via the United States Postal Service to the
non-CM/ECF participants, if any, indicated on the Electronic Mail Notice list.

I certify under the penalty of perjury under the laws of the United States of
America that the foregoing is true and correct.

Dated: August 3, 2018

/s/ Christopher M. Young
CHRISTOPHER M. YOUNG

EXHIBIT 4

FILED UNDER SEAL

CERTIFICATE OF SERVICE

I hereby certify that on June 9, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 9, 2022, upon the following in the manner indicated:

Kelly E. Farnan
Nicole K. Pedi
RICHARDS, LAYTON & FINGER, P.A.
920 North King Street
Wilmington, DE 19801
Attorneys for Defendant Kurin, Inc.

VIA ELECTRONIC MAIL

Karen I. Boyd
Jacob S. Zweig
Jennifer Seraphine
Cyndi Claxton
TURNER BOYD LLP
702 Marshall Street, Suite 640
Redwood City, CA 94063
Attorneys for Defendant Kurin, Inc.

VIA ELECTRONIC MAIL

Jonathan Hangartner
X-Patents, APC
5670 La Jolla Blvd.
La Jolla, CA 92037
Attorneys for Defendant Kurin, Inc.

VIA ELECTRONIC MAIL

Nicholas Groombridge
Catherine Nyarady
Joshua Reich
Kripa Raman
Ariella C. Barel
PAUL, WEISS, RIFKIND, WHARTON
& GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
Attorneys for Defendant Kurin, Inc.

VIA ELECTRONIC MAIL

/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)